Materials Information for Medical Device Design

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June 2007

Executive Summary

Better use of materials information changes the competitive landscape for medical device manufacturers and their suppliers. Why? And how?

Materials information impacts many aspects of design and manufacture in medical device companies: the productivity of engineers and designers; the effective re-use of prior knowledge; regulatory compliance; understanding of complex biological responses; quality processes and the ‘auditability’ of design and business decisions; enterprise-wide consistency; and the potential for innovation. In each case, both the information itself and the manner in which it is managed are important.

Poor practice in the management and use of materials information can cost millions of dollars, reduce competitiveness, and expose the company to risk. Conversely, best practice saves money, cuts time-to-market, and can help to avoid corporate liability.

Best practice solutions involve a number of requirements. These relate first to reference information. Medical device organizations need access to the widest and best range of data on: engineering and biological properties; the practicalities of applying materials; and materials usage in predicate devices. But access to this information must be optimally structured to maximize its impact on the design and development process and to be practical in complex, multi-user corporate environments. Second, device manufacturers should have a strategic approach to managing and using their proprietary data from testing, quality assurance, and product usage. They must: account for the full lifecycle of the data; ensure that it is traceable, secure, and controlled; and deploy it effectively to the people and systems that need it.

The primary components of a best practice solution are peer-reviewed, authoritative databases of published materials information, and materials information systems that integrate access to such external sources with management of proprietary materials knowledge. Predicted return on investment (ROI) is considerable. Our example calculations, based on case studies of typical materials information problems in medical device development, illustrate how ROI could exceed $15 for every $1 invested – even when only a single product opportunity or process improvement project is considered.
1. Introduction

Materials technology has a fundamental impact on the performance and viability of medical devices. Stents exploit the behavior of advanced alloys or polymers. Filters, connectors, and instruments use a variety of plastics, ceramics and alloys. A number of applications are only possible due to the properties of elastomers. Implants may employ advanced composite materials.

Orthopedic and cardiovascular applications are particularly materials intensive, with entire product innovations enabled by the material(s) used for product construction. Consider the current development of biodegradable, bioabsorbable stents. These require a complex combination of mechanical, physical, and biological response properties to ensure cost-effective manufacture, straightforward deployment, and effective, reliable use – along with the ability to degrade over time with no adverse effects. Iron, magnesium alloys, and polymers are being considered. The company that “gets it right” should establish a significant lead in the market.

Whatever the application, authoritative data on materials properties and behavior, whether from external references or proprietary testing, is essential. Figure 1 illustrates that there are implications far beyond design – including validating processes and materials for regulatory purposes, improving quality, and ensuring that marketing departments can make accurate claims about product performance.

The range and variety of materials data required to inform device manufacturing can be vast. Quantitative data can be complex. For example, materials properties may vary with temperature, chemical environment, or processing method. Qualitative information, too, can be demanding: Where and how has a material been used? Has it been approved in similar applications? Where has it been rejected, and why? What are its strengths and weaknesses?

Covering all possible device materials requires a massive quantity of information, dispersed across a huge variety of sources, and in different formats. This presents a problem, particularly since most personnel who need to make decisions based on their interpretation of this information are not materials experts. Device manufacturers who can solve this problem successfully can win considerable competitive advantage. This is especially true given the nature of the industry, with its need to balance often-conflicting goals of innovation, minimizing risk, reduced time-to-market, product safety, and product efficacy – all at optimum profit.
Materials information and its management…

**Key issues in design and manufacturing**
*(Section 2)*
- Engineering productivity
- Knowing what has been done before
- Regulatory and compliance issues
- Complexity of biological response info
- Auditability
- Consistency across the organization
- Innovation

These impact…

These have a corporate-level effect…

**Strategic business impact**
*(Section 3)*
- Time-to-market
- Product effectiveness - Customer satisfaction
- Profitability
- Quality and safety
- Regulatory compliance

These define…

These have a corporate-level effect…

**Resources and capabilities required to support best practice**
*(Sections 4&5)*
- Engineering information
- Biological information
- Coatings, drugs, devices
- Application information
- Accessing the information
- Materials data lifecycle
- Traceability
- Access control
- Change management
- Analysis & deployment

Materials reference info

Managing proprietary materials info

These define…

The result is…

**Benefits & ROI**
*(Section 7)*
- Increase competitiveness, reduce liability

These are met by…

**Best practice technologies**
*(Section 6)*
- Reference databases
- Materials information management system

Figure 2. The impact of materials information; the analysis in this paper.

2. Key Issues in Design and Manufacturing

2.1 Engineering productivity

Materials data in medical device companies is typically generated for specific projects by the department and staff that require it. This is an inefficient means of generating data that frequently leads to duplication. It also results in individual ‘pockets’ of information, with the organization’s complete body of materials data being fragmented across diverse offices, departments, spreadsheets, databases, and hard copy files. Finding and using this data is made even harder by the fact that the data storage methods used are rarely designed to handle the specific and challenging attributes of materials information. Collating all of the data, along with supporting information and experience, into a useful knowledge base to help guide future innovation, is in many cases impossible.

In a separate white paper¹, we showed how engineering organizations waste millions of dollars by treating...
materials data from testing and quality assurance in this manner. Engineers waste time looking for legacy data; materials experts generate data that goes unused; design iterations fail because of poor-quality or inappropriate data; it takes too long to trace the source of design data in response to requests from customers or regulators. Table 1 illustrates the problem. Case Study 1 (overleaf), gives an example of how such inefficiencies could affect a quality improvement investigation in a medical device company, resulting in over $1 million of avoidable cost on a single project. The aerospace industry is notable in having taken steps to address these issues, resulting in procedures and technologies to maximize the return on investment in materials. The opportunity exists for medical device companies to obtain similar benefits.

Table 1. Quotes from co-author’s interviews2 with medical device engineers.

<table>
<thead>
<tr>
<th>Quote</th>
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<tr>
<td>“The number of times I need to go back to lot history data and inspection data and have to spend hours looking for it… in fact, I often can’t find it at all!”</td>
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<tr>
<td>“We must spend half our time duplicating tests”</td>
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<tr>
<td>“Often I want to go back to a curve to extract data for Excel or Minitab and can’t find it because of the location it was saved in, or because the staff member who originally created the data has left.”</td>
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</table>

Speaking about the potential benefits of improved materials data management: “I could put in a request for all tests that have resulted in specified mechanical properties. This would immediately reduce the size of my DOE [design of experiment] or immediately focus in on a likely process without having to start at the beginning all the time.”

There is also scope for significant efficiency improvements in accessing and using external reference information. An exhaustive literature search to investigate the suitability of a specific material for a device, or to establish a material’s properties, can take days, especially if suppliers have to be contacted, specific documents ordered, or additional specialists consulted. This time can be greatly reduced if sufficient expert effort has first been directed into collating, validating, and organizing the relevant information, and presenting it in an easy-to-use format. Such an effort is likely to be beyond the scope of most individual companies, but it is achievable if the cost is shared across the industry, for example, through a commercial service.

### 2.2 Knowing what has been done before

Designers aiming to make “the next advance” need to exploit all available existing knowledge – whether external information in the scientific literature and in competitors’ product approvals, or historical in-house knowledge from their own company.

In the first category, materials information relating to predicate devices that have already been approved is particularly valuable. Knowing what has succeeded before, particularly in applications to regulatory bodies such as the FDA, not only saves development time, it can also smooth the regulatory process and generate new ideas.

This logic applies equally to proprietary data, information, and knowledge. Easy access to in-house data from past projects means that a materials expert, for example, can quickly see whether a particular test has been done before, and review its results. In another quote from the interviews referenced in Table 1, it was noted that such improved access “…would be really useful when we are starting a new product and process that is similar to previous work. We never use historical data for validations; I think we could use historical data that comes from other products using the same process, e.g., validating a particular heat treatment.”

In new product development, if a designer finds that a material is used in another of the company’s products, he or she may be able to re-use elements from that design – especially if there is direct access to the material’s properties, biological response results, and relevant FDA classifications. Knowing what has failed before can be even more valuable, helping to accelerate the development process and avoid costly late-stage failures during approvals or trials.

### 2.3 Regulatory and compliance issues

The combined management of external and proprietary materials information is very important in working with regulatory bodies. Reference information, particularly relating to predicate devices, helps to make a submission more robust. However, such information is not sufficient. The regulator will look for data specific to the device and to the processing and loading history of the material. The FDA, for example, expects a submission to demonstrate a thorough understanding of how processing factors may affect the final device. Submitting companies need to show a comprehensive body of supporting data and analyses, with a reliable pedigree, that validates the materials properties quoted for different processing regimes. Appendix B provides two further examples from an FDA Guidance Document of the materials data required in a submission. Approval will be delayed if a regulator’s query cannot be immediately answered with reference to the source data and analyses.
Case Study 1
Productivity savings in tracking down a quality issue

Six sigma is a favored quality measurement and process improvement program in the medical device industry. One six sigma approach uses a cross-functional group known as a DMAIC team. The acronym stands for Define, Measure, Analyze, Improve and Control. This case study concerns a hypothetical medical device OEM seeking to address a quality problem. How is the DMAIC process affected by materials information, and how might it be improved?

By conventional current practice, the following might be the sequence of events:

**Define** – the problem is ‘Product fall out due to low and inconsistent material strength measurements, following the final processing step of manufacture’.

**Measure** – the team sets out to analyze data from past production runs. After some months of data mining and analysis they conclude: “Gathering all this data from our current systems is impossible. It would be easier to generate new data from specific experimental lots’. Some analysis has been completed, but the results are not statistically valid because the data is incomplete. So the team specifies additional production runs purely for data generation. This process takes eighteen months and requires a dedicated pilot process plant.

**Analyze** – analysis of the mined and new project data is a monumental task. The team leader spends 80% of his time creating spreadsheets, generating curves and trend lines, and trying to enhance the data. The process is hampered because some members of staff are no longer with the company. Their data is lost in complex filing systems. After much manual labor, analysis is complete, and the root causes of the quality issue are identified.

**Improve/Implement** – the improved process is implemented 24 months after the project began. However, continued data collection and correlation with predicted and historical data is essential during implementation. This is difficult because it remains time-consuming to capture data and consolidate all of the necessary data in a single place for analysis.

**Control** – monitoring employs spreadsheets that are unique to the process. Few people working on other products (even other DMAIC teams) are aware of them.

How could this wasteful and time-consuming process (itself required to investigate and correct the original process issue) be avoided? Effective materials data management, integrated with analysis tools, could radically reduce the time to collate and mine data. If best practice materials information management were in place, data collection in the implementation phase and feedback to materials analysis would be automatic, while the monitoring data would also be available immediately for use enterprise-wide. It is estimated that the project time could be cut in half. In Appendix A1 we show the derivation of our estimate that the potential financial benefit to the company would be over $1.5 million, purely as an efficiency saving on this single project.

So, ready access to all supporting materials information of suitable pedigree is a key component for successful regulatory submissions. The on-going development of a body of reliable, traceable, property data can also reduce the need to generate additional data in support of new submissions. And it creates a knowledge resource that can be mined for innovative new design possibilities.

2.4 Complexity of biological response information

Selecting a material that satisfies specific mechanical and physical design requirements, is straightforward to process, and is cost-effective can be challenging enough. Add the requirement to remain undamaged by extensive operation in the *in vivo* environment, and we have the additional need for biochemical understanding. One option is to put a coating on the component – thus enabling cheaper (or lighter, or easier to manufacture) core materials to be used for the component structure, provided the coating effectively isolates it from damaging environmental exposure. This increases the number of potential options to (x materials) times (y coatings), although not all combinations will be possible. And if the device is intended to be drug-eluting, the coating will also need to be compatible with the relevant drugs as well as with the material and manufacturing process, and be able to operate *in vivo*.

It is much easier to navigate this complex set of parameters if the right knowledge has been abstracted and compiled by subject matter experts, and if user-friendly tools are available to apply that knowledge systematically, helping users to converge on the subset of materials possibilities that merit more detailed assessment.
2.5 Auditability

Medical device companies make decisions by combining materials property data with analysis methods, with their business rules, and with human judgment. Decisions must be open to audit: by regulators; for legal reasons; by the OEM if the company is a supplier of sub-components; to facilitate good customer service (for example, speedy diagnosis of a problem); and for continuous product improvement.

This requires traceability. For example, the pedigree of a piece of design data must be traceable to its source test data and analyses. But auditability is not just about efficiency in following a linear trail. It is also important to capture as much as possible of the context for a decision: Why and how was it made? What alternatives were considered/rejected? What qualitative and quantitative factors were considered? To what other decisions does it relate? This requires many different types of information – property data, functional data and algorithms used in analyses, process documents describing business rules, and notes recording the reasoning behind judgments. And it is equally important to record all of the relationships between these objects.

In many medical device companies today, if this context for a materials-related decision is captured at all, it is likely to be done in a notebook or report document. If references are made to information held in other systems, it can often be difficult to ‘join the dots’. Auditability would improve dramatically if materials property data were stored in a single system and integrated with the rest of the company’s business-critical information and systems.

2.6 Consistency across the organization

There are further examples of the need to connect the company’s materials data to other business systems. In design, for example, behavior of a device will be simulated using computer-aided engineering (CAE) tools. These require materials data as inputs, formatted in highly specific materials models. It is important to ensure that their users apply only up-to-date, company-approved data, ensuring accuracy and quality, and guaranteeing consistency – so that calculations made by two members of a project team are reliable and comparable.

Such consistency is also important where organizations seek to implement strategic decisions relating to materials. For example, a company may decide that it will only use a limited set of plastics in its devices – perhaps to pursue economies of scale, due to business relationships, or for regulatory reasons. Making such decisions a reality requires the list of preferred materials to be created and maintained, and integrated with the tools and processes used in procurement and design.

Approved materials data must be easily accessible to its potential users across the enterprise and throughout the product lifecycle.

2.7 Innovation

We have already seen how an efficient system for mining materials data helps designers to re-use prior knowledge. But it can also feed innovation by ensuring that all relevant materials data is captured, consolidated, and open to analysis. Such data mining supports, for example, the goal of continuous improvement that is central to the culture of successful medical device companies.

Innovation through systematic materials selection provides a further example. A designer may need to determine a substitute for a device material that has become too expensive or subject to new regulations. Or a design change such as moving to a smaller structural cross-section may force a re-think in order to retain the required strength. The most rigorous approach is to start with the widest possible set of allowable materials and to focus-in on the best candidates. First, the constraints imposed by the application must be considered – for example, that the material must be sterilizable, or compatible with a particular processing technique. Next, key design objectives are explored – perhaps, to maximize strength in bending while minimizing cost. The materials that best balance these objectives can then be identified for detailed analysis. Software-based materials selection methods developed by Professor Mike Ashby at the University of Cambridge (figure 3) allow such exercises to be completed rigorously and quickly.
Materials information plus the right software tools can drive innovation.

3. Business Impact

At the corporate level, the impact of materials information is felt in its effects on the company’s competitiveness and on its capacity to manage liability.

3.1 Competitiveness

Time-to-market – being first-to-market can be essential to the success of a medical device product. The first entrant can lock out competitors through patent protection and by establishing a strong market position. And, whether a company is first or not, delay can mean millions of dollars in lost sales or market share. A McKinsey & Co. study reported that a six-month delay could reduce profits by 33% over the product lifecycle. The global market for cardiovascular stents, for example, is estimated at $6 billion p.a. and dominated by two manufacturers. If a new device from a third large player hoped to gain 10% share within the first month, then each day lost costs over $2 million!

So anything that shaves time from design and development phases can have a major impact. We have shown how problems with materials information can cost weeks or even months by reducing engineering productivity and leading to unnecessary duplication of work. Conversely, good practice can enhance innovation and offer insights that could dramatically reduce time-to-market. Regulator approval can also cause major delays, but once again good use of materials information helps to smooth this process. In short, a company dedicated to minimizing the time taken to turn concepts into marketable products needs to examine how it manages its materials information.

Case Study 2 illustrates how a medical device supplier could have avoided the multi-million dollar costs of late delivery.

Case Study 2
Process validation for a device component supplier

(Case study developed from: FDA Process Validation Guidance – SG3.N99-10, FDA briefing presentation from Christine Nelson, Center for Devices and Radiological Health, and supporting information from Interviews)

A medical device component supplier is developing a process to make polymer components for a new device. The supplier has 9 months to establish a ‘Validated Process’ before they begin shipping $1 million of product per month to an OEM partner. Process validations are integral to device manufacturers’ quality systems. The steps are:

1. Installation Qualification (IQ) – i.e., initial assessment of the equipment.
2. Operational Qualification (OQ) – confirm that the process always results in an acceptable product within process input limits.

Data is collected and statistically analyzed during these phases using methods such as Failure Modes and Effects Analysis (FMEA), Design of Experiments (DOE), and Capability Studies.

In this case, the OEM sets a very tight specification. Validation is carried out as a standalone procedure, with the protocol and testing designed and performed for the specific product. Starting from scratch in this manner against such strict criteria requires many months of experimentation and process design. Much of this could be avoided through use of historical data for IQ, OQ and PQ. But such data cannot be used in this case because:

The data is fragmented – it is held in diverse inspection records, audit records, failure investigation reports, logbooks, and lot records. Although the final processing parameters have been employed on many previous products, the team cannot search all combinations of desired properties against previously established data. It is even known that the process parameters have been tested on previous products, but finding the data is described by the engineer in charge of validation as “virtually impossible”.

Multiple manufacturing sites and suppliers mean that the team is not aware of the useful data that is available.

Data is not recorded in sufficient detail or in a manner that would facilitate a validation – for example, a simple statement of “pass” or “fail” is rarely adequate.

Validation is eventually completed after 13 months, 4 months behind schedule. Had it been possible to use historical data effectively, it could have been completed on time. We estimate (Appendix A2) the direct costs of delay as $288,400. Lost sales would be $4 Million. The long-term damage to the supplier’s relationship with the OEM could be more costly still!
Case Study 3
Cardiovascular device design and FDA submission


A cardiovascular OEM is seeking to design a new vascular stent and get FDA approval. The OEM is not using best practice materials information management. What issues arise?

The FDA regards handbook and ASTM tabulated data, without further supporting data, as unacceptable. So the submission needs to demonstrate thorough understanding of processing history and its effect on the product (Appendix B - Table 1). Testing must be fully validated with appropriate protocols and documentation (including raw data – Appendix B - Table 2). The alloys used in vascular stents are well documented and thoroughly characterized. But figure 4 shows how their properties vary depending upon processing and loading history in the deployed device. The submission must provide properties for the specific geometry, processing, and conditions of use of the stent, with complete supporting data. Inefficient materials data management means time is wasted in collating, discussing, and analyzing this data, and preparing reports that link submitted properties to source data.

The issue of the safety factor for fatigue life and device durability poses a particular challenge. The FDA reviews these by a ‘qualitative synthesis’ of relevant data. With the industry moving towards ‘test to failure’ protocols for submissions and away from ‘test to success’, safety factor calculations are becoming increasingly important. Stress analyses on new stent designs are vital to justifying these factors. In our example, the OEM needs to show that its design falls well within acceptable literature values – but by current practice finds that the volume of data available to it is not great enough to make this case. A lot of extra testing is required in order to reduce the statistical variance on the measured properties.

Our calculations in Appendix A3 show how savings could be made through more efficient consolidation and analysis of data in design and reduced testing. The time saved would cut time-to-market and generate more revenue. We estimate an on-going saving of $438,000-worth of engineering time and materials per year on the overall process – with potential increased profitability of $2.5million on the example stent, based on a 4-week reduction in time to market.

Customer satisfaction – given that the regulatory process ensures safety, the healthcare professionals and organizations that specify and use devices are looking for effectiveness, reliability, and excellent supporting service. Materials information helps inform better design decisions, which can be an important factor in both efficacy and reliability – for example, making the component more flexible and easier to deploy while retaining its strength, or guaranteeing or even extending its usable life. Quality of service can be determined by the organization’s ability to respond to queries or to customize the product. Both may require rapid and complete access to the data and analyses that characterize the material’s behavior as specified in the design.

Profitability – time-to-market and customer satisfaction are among the key determinants of the market share that a company can gain and then retain, and thus of its annual revenues. Case Study 3 shows how reducing delays in design, testing, and FDA submission by just 4 weeks could translate to over $2.5million in extra margin for an OEM bringing new cardiovascular devices to market.

As well as generating more income, we saw in Case Study 1 how productivity enhancements can reduce costs by seven figure sums. Another obvious, but nonetheless significant, cost is the purchase price of materials themselves. Materials information technology can help to systematically define and then implement
strategies to ensure that the most cost-effective materials are specified for each function.

3.2 Corporate liability

Quality and safety – using incorrect or inconsistent materials property data in design, unwittingly repeating known problems, making poor materials selections: these are all possible consequences of bad materials data management. In the best case, the result is lower product quality. In the worst case, the result can be a product recall, with disastrous consequences for the company and its customers. More likely is that flaws will be exposed during design, testing, or trials. Failures detected early in this process simply waste time and cost. Later-stage failures can mean much more substantial losses, coupled with damage to the company’s reputation.

Regulatory compliance and inspection – we have discussed the positive impact of a smooth regulatory process on time-to-market and on costs associated with submission. Medical device companies also wish to avoid adverse events, such as an FDA warning letter. These can be triggered by problems with a design or inaccuracies in its documentation or marketing – and once again one of the sources of these can be inaccurate or badly managed materials information. Manufacturers need to avoid such incidents, not only because they indicate failures in process and possibly in safety, but also because fixing them can be a major drain on resources, and because they seriously damage the company’s brand.

Best practice use of materials information, then, is one insurance policy against such risks. What is required for such best practice? There are two elements to the solution – structured and easy-to-use access to the right reference information, and effective management of proprietary data. The next two sections of this paper examine the requirements in each area.

4. Resources and Capabilities Required to Support Best Practice

4.1 Engineering information

The first, and obvious, requirement is for engineering information on the different materials types – plastics, alloys, composites, ceramics – that may be used in medical devices. This data is specialized and complex. Even storing the name of each material requires a system to cope with different alloy compositions, grades of polymer, heat treatments of the same material, and so on. For each material, there are dozens of relevant properties, such as engineering properties, biological response information, process performance qualification, and in-vivo fatigue life. Each property has its own conventions, units, measurement techniques, and other subtleties. A property may be represented by a single number, by a range representing its possible variation, or by a graph showing how it varies with parameters such as temperature or chemical composition. The graph may be defined by an expression, or by perhaps several thousand individual data points – and its axes may be defined on linear and/or logarithmic scales.

A truly effective materials information system must be able to collate, hold, analyze, and connect all of this data. Generic information systems or tools designed for financial or general administrative information do not cope well with these advanced and highly specific requirements. Specialist systems are required.

4.2 Biological information

As noted in section 2.4, the need to consider biological response data adds an additional dimension to the information required to specify materials in medical devices. There are a number of challenges:

- Just as with engineering data, the information may be in complex scientific formats
- Especially for information relating to technologies that have not yet been approved in existing devices, this data exists primarily in the scientific literature – and thus (a) can be difficult to locate and keep abreast with and (b) primarily involves written documents, with the data or graphs embedded in the text
- The scientific data is invariably not presented in a format intended for design engineers – with categories including:
  o Degradation behavior in body fluids
  o Blood compatibility, such as thrombogenicity
  o Soft and hard tissue response
  o Local and systemic toxicity, carcinogenicity, etc…
- As noted in section 2.4, complications arise from the need to consider material, coating, and potentially drug interactions, and to screen out non-viable combinations

The requirement here is not to by-pass the role of biochemical and bioengineering experts, but rather to provide a means of abstracting and providing an overview of the above topics compiled by subject matter experts to assist the initial screening exercise and help to converge on the subset of possibilities that merit more detailed assessment.
4.3 Application information

Finally, the designer needs information on the material in use – both qualitative information, such as where it has been used, and quantitative data on the actual materials properties measured while in use. The same requirements apply to this information as in the earlier discussions of engineering and biological information. The challenges in all of these are in gathering the data from the broad range of sources on medical device applications, maintaining this data, and presenting it in a format that is suitable for its intended users.

4.4 Accessing the information

The next question is: what does the designer require in order to access the data? First, data must be simple to find – preferably by integrating access into a single system or portal. This can be achieved either by consolidating related information – for example for a particular subject, materials type, or application – or by accessing multiple databases from a single location. The key is to make this ‘one stop shop’ simple to use – e.g., via a web browser user interface. And access usually needs to be shared between many users. This requires:

- **Interactivity** – it must be quick and easy for every user to search and browse the data, and to explore the relationships between items of data.

- **Scalability** – speed must be maintained as the number of users and sites grows.

- **Practical cost and licensing** – sharing data across many users must make commercial and administrative sense.

- **Integration with application software** – it must be easy to transfer data to FEA and other applications.

- **Integration with other data** – it must be possible to combine and compare data from different references and from proprietary in-house sources.

- **Pedigree and traceability** – data should be linked to source data or documents.

- **Access control, change control, quality control** – a range of other data management issues are critical to deploying high quality information across an enterprise.

Studies of many engineering organizations that have sought to improve their use of materials information demonstrate that such issues are vital. Solutions founder when they focus purely on data content without considering the organizational, business process, and human factors that determine whether and how people will use the data. One project that has comprehensively analyzed these issues is the Material Data Management Consortium\(^8\) (MDMC), a collaborative project of 15 top engineering organizations. Members such as NASA, GE, and Rolls-Royce are primarily in the aerospace and energy sector, but the lessons they have learned apply across industries – and particularly to the medical device industry, where liability issues are so important.

5. Best Practice in Managing Proprietary Information

5.1 The materials data lifecycle

The MDMC has defined ‘the materials data lifecycle’ – (figure 5), a simple description of what happens to materials data within the engineering process.

Data is captured and consolidated from external sources, internal testing, or legacy databases. It is

![Figure 5. The materials data lifecycle.](image)
Table 2. Requirements for materials data management.

<table>
<thead>
<tr>
<th>Capture</th>
<th>Analyze</th>
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<tbody>
<tr>
<td>• Handle the specifics of materials information, including numerical property data, graphs, images, text, and literature reference formats</td>
<td>• Integrate access to key materials data analysis methods and make their use simple</td>
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<tr>
<td>• Create a single, consistent portal for all materials information (from external publishing, internal testing, product performance legacy)</td>
<td>• Provide the statistical and graphical tools to deal with typical materials information formats</td>
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<tr>
<td>• Enable easy import and export of data, especially from common test equipment and information sources</td>
<td>• Ensure that the system is open to easy integration of new, or proprietary in-house, analyses</td>
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<tr>
<td>• Capture and retain pedigree information on all data and analyses. Link related information, so that it is easy to trace.</td>
<td>• Provide facility to link analyzed data to external references, while retaining full traceability</td>
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<tr>
<td><strong>Deploy</strong></td>
<td><strong>Maintain</strong></td>
</tr>
<tr>
<td>• Provide intuitive access to the information that users need, where they need it, in the format that they want.</td>
<td>• Support frequent (and, if required, automatic) data updates from the latest lab tests</td>
</tr>
<tr>
<td>• Fit the workflows of key users - e.g., provide data in the correct formats directly to FEA programs</td>
<td>• Ensure regular updates from external reference sources</td>
</tr>
<tr>
<td>• Guarantee security (i.e., users can only view data that they are authorized to see)</td>
<td>• Preserve corporate knowledge by capturing not just data and information, but also their context</td>
</tr>
<tr>
<td>• Control data integrity (certify it as up-to-date and accurate)</td>
<td>• Enable easy response to changing standards, operating systems, and user needs</td>
</tr>
<tr>
<td>• Ensure system is robust and scalable to many users, enterprise-wide</td>
<td>• Share the cost of essential developments</td>
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Analyzed, usually by materials experts, to create approved information that is suitably formatted for access and use by, for example, designers and simulation engineers, to whom it is then deployed. And the whole system – the data and information generated, and the relationships between them – must be constantly maintained. Some practical requirements for each of the four stages of the lifecycle are identified in Table 2.

Let us examine some requirements that are particularly pertinent to medical devices.

5.2 Traceability

We have discussed the importance of traceability in enabling auditing of data for regulatory, customer, and product design purposes. This requires any materials information system to have at its heart a sufficiently sophisticated yet flexible database – one that can capture and maintain the relationships between the potentially complex items of data noted above. There are three aspects to successful implementation, in information technology terms. The database developer should:

- start with a purpose-built materials information system, rather than a “raw” database system. The ability to handle all of the complexities of materials data should be built in, enabling the following steps to be carried out as a configuration task by materials information experts, rather than requiring programmers to write specific new software.
- create the specific database design – known as the schema – that defines and organizes the various types of materials data that the database will need to store, and the connections between them;
- create tools to manage these data and relationships – for example, allowing users to define and implement rules that enable automatic generation of a link between an imported material design property and the test data from which it was derived.

Developing a schema (figure 6) and tools that are sufficiently tailored to a specialist area such as materials for medical devices, while retaining flexibility to deal with the needs of individual organizations, requires a rare blend of materials domain knowledge and
information technology expertise on the part of the system provider.

5.3 Access control

Control of data is essential to medical device companies. Not only do they need to protect valuable confidential data, they also need to make sure that designers use only approved data, and to preserve carefully defined institutional boundaries – for example, between the design and testing phases of the development cycle. There is also an important usability issue for applications where users require data from a relatively limited set within a much larger database – use of the system is much easier, and faster, if only relevant data is presented. Materials information systems must have the ability to identify individual users and to serve them only with data that they are authorized to see or to edit.

5.4 Change management

Materials information and the knowledge that relates to it are not static. Data changes as knowledge of the materials’ behavior evolves. New data is produced. Analysis methods, business strategies, and corporate objectives also change. This is particularly true in the fast-moving world of medical devices, where change can be driven by new regulations, medical breakthroughs, or competitive activity. The latest database technology helps us to identify the impact on related objects in the database when one item changes. Information systems for medical materials should make full use of this capability by providing tools that, for example, highlight products using a particular material when approval for its use is withdrawn, or recalculate materials selection decisions if a business rule applied during the original selection process is modified.

5.5 Analysis and deployment

Finally, there is little point in an excellent system to store and maintain materials data if no one can do anything with it! It is important to consider the needs and workflows of everyone who may wish to analyze or use the data. In a medical device company there is likely to be a relatively small but important number of materials experts with specialist analysis needs. The system needs to address their requirements while not confusing or deterring the much larger number of designers who simply wish to find and apply design data. This may require that the system offer different ways to access different views of the data and different tools to apply it.

Materials experts, for example, are likely to invest time and effort in learning specialist tools that will assist their function, and may therefore need the in-depth functionality that can be offered by a dedicated Windows® application. Conversely, the key requirements for designers are intuitive search utilities and an effective means to browse the results – capabilities that can be provided to a broad user community via a web browser. Finally, engineers and analysts doing more intensive design work within FEA software need to import data directly into those systems. The overall solution needs to be designed for real users and representative use cases, based on practical experience of device design.

6. Example Solutions

The requirements that we have identified for materials information technology lead to two, related, system components – knowledge content in the form of databases of materials information, and associated integrated software systems to manage and enable data access and selection from that materials information. We will describe a leading example of each.
6.1 Knowledge content – The Materials for Medical Devices Database

The Materials for Medical Devices Database\(^*\) (fig 7) is the only comprehensive database created specifically for medical device design. Its first, Cardiovascular, module was released in early 2007 providing researchers and designers with a comprehensive and authoritative source of materials property data, biocompatibility data, drug compatibilities and surface treatment methods for the materials, drugs, and coatings used in cardiovascular devices (specifically, as listed under USFDA part 870 subchapter H Chapter 11, Title 21).

As discussed in section 2.1, such a resource must be backed by a significant, credible, and ongoing effort to collate, organize, and index relevant information. In this case, the database results from thousands of hours of data acquisition, peer-review, and verification by specialists, supported by investment from ASM International, the US materials information society, and Granta Design, a University of Cambridge spinout and leading authority in materials information technology. An advisory committee of industrial and academic experts (table 3) guides development.

All of the data is fully traceable to its sources. It includes thousands of citations to published literature, FDA device approvals, manufacturers’ datasheets, and web sites. It aids the identification, screening, and selection of material grades, manufacturing processes, and suppliers for applications from drug-eluting stents to nerve stimulators to replacement heart valves. The database can be accessed across the Internet or installed on a corporate network. An access fee funds the continued development and updating of the database. This shared investment model enables a unique information resource with the scale, scope, and currency required in this fast-moving market.

Table 3. Materials for Medical Devices – ASM Steering Committee.

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Michael Helmus</td>
<td>Committee Chair, Senior Vice President, Advance Nanotech, Inc.</td>
</tr>
<tr>
<td>Mr. Stanley Abkowitz</td>
<td>President &amp; Technical Director, Dynamet Technology, Inc.</td>
</tr>
<tr>
<td>Dr. Steven Arnold</td>
<td>Senior Research Engineer, NASA Glenn Research Center</td>
</tr>
<tr>
<td>Dr. Kelvin Brockbank</td>
<td>Senior Vice President, Organ Recovery Systems</td>
</tr>
<tr>
<td>Dr. Arthur Coury</td>
<td>Vice President of Research, Genzyme Corporation</td>
</tr>
<tr>
<td>Dr. Donald F. Gibbons</td>
<td>Corporate Scientist (Retired), 3M Biosciences Laboratory</td>
</tr>
<tr>
<td>Dr. Martin King</td>
<td>Professor, North Carolina State University</td>
</tr>
<tr>
<td>Dr. Frederick Lisy</td>
<td>President, Orbital Research Inc.</td>
</tr>
<tr>
<td>Mr. Y. V. Murty</td>
<td>Director, Research &amp; Development, CMI Incorporated/University of Virginia</td>
</tr>
<tr>
<td>Dr. Jack Parr</td>
<td>President, Medical Technology Development, Inc.</td>
</tr>
<tr>
<td>Mr. Todd Smith</td>
<td>Director of Research, Dupuy Inc.</td>
</tr>
<tr>
<td>Dr. Sanjay Srivastava</td>
<td>Principal Engineer, Abbott Vascular</td>
</tr>
<tr>
<td>Dr. Charles Sturrock</td>
<td></td>
</tr>
<tr>
<td>Dr. Dave Williams</td>
<td>Professor of Tissue Engineering, University of Liverpool</td>
</tr>
</tbody>
</table>
6.2 Materials information management software – GRANTA MI

GRANTA MI™, from Granta Design, is the leading software system for materials information management in engineering enterprises. It is built around an advanced central database, designed specifically to handle materials data. Engineering organizations use this system as a single information resource in which they combine data from in-house testing and design, proprietary sources, and external references. GRANTA MI provides a wide range of specialist tools to capture, import, analyze, and apply this data.

Materials experts use GRANTA MI to manage, analyze, certify, and maintain materials data, publishing their results in a secure and controlled manner. Engineers, designers, and other professionals can then access and apply this information easily within their routine workflows, assured that it is relevant, traceable, and the best available. Such data users can access the information that they need through a simple browser-based interface, while materials experts perform more intensive processing and analysis tasks via dedicated Windows applications. GRANTA MI’s application programming interface (API) technology enables third party software, such as FEA tools, to connect to the database so that their users can extract data directly.

Granta customers, including medical device companies and members of the Material Data Management Consortium, have guided the development of GRANTA MI. It meets the requirements outlined in section 5 – controlling access for different users, providing traceability, and automatically generating links between related items of data. GRANTA MI’s materials strategy software module also helps companies to make and implement materials-related decisions – both individual design decisions, such as which material to use for an application, and strategic business decisions, such as establishing a list of preferred materials. Such tools also have a significant role in cost avoidance and in facilitating innovation.

7. Assessment of Benefits and ROI

7.1 Qualitative benefits

The main benefits follow from the ability to address the tactical issues outlined in section 2, as illustrated in Table 4.

Table 4. How best practice materials information technology addresses key issues for medical device organizations

<table>
<thead>
<tr>
<th>Issue</th>
<th>Benefits of a comprehensive, authoritative database (Materials for Medical Devices)</th>
<th>Benefits of an enterprise materials information management system (e.g., GRANTA MI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhance engineering productivity</td>
<td>Quick, easy online access via a single portal to relevant materials information – saves time searching multiple sources and collating the results.</td>
<td>Greatly reduces time lost in collating, processing, managing, deploying, searching, and using proprietary data.</td>
</tr>
<tr>
<td>Knowing what has been done before</td>
<td>Easy-to-use single reference for public-domain knowledge – reduces unnecessary work by confirming what has been approved in predicate devices, and linking directly to the associated materials and biocompatibility knowledge.</td>
<td>Ensures that all relevant corporate information is easily found and used – greatly reduces unnecessary work and enables all design teams to benefit from “lessons learned”.</td>
</tr>
<tr>
<td>Regulatory compliance</td>
<td>Access information about materials in previous FDA approvals online – reference relevant predicate device knowledge in new submissions.</td>
<td>Demonstrate best practice in internal materials information management.</td>
</tr>
<tr>
<td>Innovation</td>
<td>Generate ideas based on previous experience, including potentially novel solutions by systematic analysis of materials in other device applications.</td>
<td>Marshall all relevant proprietary and published information and apply systematic techniques for materials selection.</td>
</tr>
<tr>
<td>Complexity of biological response information</td>
<td>Easy online access to extensive information, including material/coating/drug compatibilities and links to engineering properties.</td>
<td>Data of all formats – numerical, textual, graphical, pictorial, and hyperlinked – may be readily captured, collated and made available for searching and use across the enterprise.</td>
</tr>
<tr>
<td>Auditability</td>
<td>Provides comprehensive references and direct links to original data sources and literature publications.</td>
<td>Enables full data traceability from design reports and FEA analyses back to individual lab test results.</td>
</tr>
<tr>
<td>Consistency within the organization</td>
<td>A single portal to external reference data, with systematic search tools enabling consistent usage across the enterprise.</td>
<td>A single, consistent “gold source” of approved, proprietary materials knowledge, plus software tools enabling consistent access to, and use of, this data in different user applications and workflows.</td>
</tr>
</tbody>
</table>
Table 5. Financial benefits of materials information management from case studies.

<table>
<thead>
<tr>
<th>Case study</th>
<th>Description</th>
<th>Time</th>
<th>Financial benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Productivity savings for an OEM in a quality improvement process</td>
<td>Improved productivity and elimination of unnecessary manufacturing and testing</td>
<td>24 months project reduced to 12 months</td>
<td>$1.5 million cost saving in this one project</td>
</tr>
<tr>
<td>2. Process validation for a device component supplier</td>
<td>A 4-month delay on a 9-month validation project could have been avoided</td>
<td>13 months reduced to 9 months</td>
<td>$288,400 in direct cost saving in the project. Avoidance of $4m revenue shortfall</td>
</tr>
<tr>
<td>3. Cardiovascular device design and FDA submission by an OEM</td>
<td>On-going reduction in time for design, testing, and approval submission</td>
<td>On-going for the overall process. 4 weeks reduction in time-to-market for example product</td>
<td>$438,000 in direct cost saving on overall process per annum. $2.5 million additional profit on the example product</td>
</tr>
</tbody>
</table>

7.2 Quantitative benefits

In Case Studies 1-3 above, we derived estimates of the potential financial benefits. We can compare these numbers to the typical costs of materials information management implementations, to generate an idea of return on investment (ROI).

Appendix A details the simple models used in the case studies, and the results are summarized in Table 5.

Each of these case studies illustrates different aspects of effective materials information management. The cost bases are different, and the companies are likely to be of different sizes, with the component supplier in Case Study 2 perhaps being smaller than the OEMs in Case Studies 1 and 3. Nonetheless, we see cost savings of from $288k to $1.5M on a single project, with additional profit (or avoidance of lost profit) opportunities of $2.5M to $4M, again for single, specific product examples.

The diversity in the examples (plus the need for further significant assumptions, in scaling up from individual projects to company-wide) makes a single ROI figure difficult to define. However, how much does it cost to implement such best practice? Table 6 gives indicative figures for a medium-sized medical device company. Both investment and return figures will scale up or down for larger or smaller organizations.

All of the assumptions notwithstanding, we can readily see that simply on cost savings from a single project alone, the ROI could range from break-even to around 5:1. Consider also the additional profit opportunity, and the total ROI could jump to 15:1 – and again on the basis of only a single product! We leave the reader to consider the number of parallel products/projects that it would be relevant to include from his or her organization.

8. Conclusions

8.1 Time to learn from other industries...

There is a strong case for materials information technology in medical device companies. But such solutions are not yet in widespread use. Why not?

Table 6. Typical costs of best practice materials information management.

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost per annum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual software investment (includes maintenance, support, upgrades)</td>
<td>$100k</td>
</tr>
<tr>
<td>Administering the system: equivalent of three-quarters of one full-time employee (likely to be shared between materials and IT expertise) including overheads</td>
<td>$140k</td>
</tr>
<tr>
<td>Startup costs (implementation, data transfer etc.): assume 3 employees / consultants for 3 months = 9 person-months= $140k. Amortize over 5 years.</td>
<td>$28k</td>
</tr>
<tr>
<td>Dedicated hardware cost (equivalent per year)</td>
<td>$7k</td>
</tr>
<tr>
<td><strong>Total per annum</strong></td>
<td><strong>$275k</strong></td>
</tr>
</tbody>
</table>
We believe it is a combination of factors:

- Historically, the medical device industry has taken a conservative approach to innovation, due to the significant regulatory requirements and liability implications of product failures.
- Meanwhile, margins in the industry have been good, and companies have not had the same requirement to chase ultimate efficiency as have companies in other sectors.
- Possibly in reaction to the above, until recently there has been relatively limited focus on the medical devices sector on the part of materials information technology specialists.

In today’s environment, however, the ever-increasing demand to manage legal exposure and to reduce healthcare costs is in turn pressuring medical device manufacturers to become more efficient, cost-effective, innovative and competitive. These drivers have long been familiar in other industries – and regarding materials information, the aerospace industry in particular has reacted aggressively in recent years through the Materials Data management Consortium mentioned in sections 4 and 5. Companies involved in that initiative are enjoying the benefits outlined above (and in our related paper). It is time for the medical devices industry to take advantage of today’s technologies – especially as initiatives like the Materials for Medical Devices database are delivering unique products directly targeted to their requirements.

### 8.2 Summary of benefits

There is a strong financial case for effective materials information management in medical device companies. Since there is such a strong connection between the performance of the material, and the success and cost-effectiveness of the device, this is a topic that device manufacturers cannot ignore. And, aside from helping avoid catastrophic errors, what price fueling creativity, and increasing the chances of breakthrough insights in innovative product development?

The likely ROI could exceed $15 for every $1 invested, on a single product program alone.

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**References**


2. Morgan N., personal communications with medical device engineers in industry


8. The Material Data Management Consortium, [www.mdmc.net](http://www.mdmc.net)


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GRANTA MI and CES Selector are trademarks of Granta Design Ltd.

Windows is a registered trademark of Microsoft Corporation.
Appendix A – Financial Return Calculations for Case Studies

As noted in the Introduction, each of these “case studies” represents an aggregate of components collated from interviews with a variety of device companies, and other sources. For simplicity, we have assumed a working year to be 42 weeks/1680 hours for the companies in each of the examples.

A1. Case Study 1 – Productivity savings in tracking down a quality issue

We assumed the following staff were employed:

- Full time project leader at manufacturing engineer level earning $80k per annum, with 135% fixed overhead cost = $112/hour
- 2 full time skilled operators at $26/hour + 135% fixed overhead = $61/hour each
- Time spent on the project by 8 other DMAIC team members, including review by upper management and other engineers, totals approx 7 hours per week per team member, at an average cost including overheads of $200/hour

We also assumed costs for parts manufactured (and subsequently scrapped) for project measurements:

- Total cost of parts manufactured specifically for the project: $420,000

Finally, we assumed that the company’s goal for correcting the original process issue (i.e., by implementing the Six Sigma project) was to realize savings of $500,000 per annum by eliminating the product fallout. This saving would only be realized once the Six Sigma project was complete, and would thus represent an opportunity cost each year until then.

Based on these assumptions, the 24 month cost of the project by current methods, including the Six Sigma cost saving opportunity that cannot be realized until the project is complete, amounts to:

<table>
<thead>
<tr>
<th>Staff</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project leader</td>
<td>$376,000</td>
</tr>
<tr>
<td>Skilled operator</td>
<td>$410,600</td>
</tr>
<tr>
<td>8 other part-time team members</td>
<td>$940,800</td>
</tr>
<tr>
<td>Cost of parts made, tested and scrapped</td>
<td>$420,000</td>
</tr>
<tr>
<td>Opportunity cost of target saving</td>
<td>$1,000,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$3,147,400</td>
</tr>
</tbody>
</table>

We assessed that had the company used best practice materials information management during the original process development and the work of the DMAIC team, then this project duration could have been reduced by at least 50%, leading to the following cost savings:

- 12 months labor cost for all the team members, amounting to **$863,700**
- Assume the more efficient project process enables 40% reduction in the number of parts manufactured for project-specific measurements, equating to a saving of **$168,000**
- The implementation of the new process 12 months earlier, enabling the realization of the predicted saving in the 2nd year **$500,000**

**Total financial benefit, in this one project alone:**

**$1,531,700**

A2. Case Study 2 – Process validation for a device component supplier

We assumed that completing IQ, OQ, and PQ took 12 months of continuous experimentation on all steps of the process. In particular, the raw material and process parameters would require a significant amount of testing. We estimated that the total time and therefore cost of getting to a stage where product could be shipped was as follows:

- 13 months of a full time Process Engineer dedicated to the project earning $70k per annum with 125% fixed overhead cost = $94/hour
- 13 months of a skilled operator working in Quality and inspection to carry out mechanical testing and fatigue testing at $19/hour + 125% fixed overhead = $43/hour
- 13 months of a skilled operator working in Production to manufacture samples and support process development at $19/hour + 125% fixed overhead = $43/hour
- Time and approximate costs of other staff spent developing the process totals to approximately 20 hours per week at an average cost per hour including overheads of approximately $65/hour

We assumed the following cost for parts manufactured and subsequently scrapped for the project measurements:

- Total cost of parts manufactured during 13 month period approximately: **$400k**
Based on these assumptions, the 13 month cost of the process development amounts to:

- Process engineer: $170,600
- Quality operator: $77,800
- Production operator: $77,800
- Other team members: $59,200
- Cost of parts made, tested and scrapped: $400,000

Total: $785,400

We assessed that, had the company applied best practice materials information management to its historical data, the validation step could have been completed within the 9 months time targeted. The potential cost saving in terms of operational labor hours and manufactured parts could be estimated conservatively as:

- 4 months labor cost of all team members, $128,400
- Assume the more efficient project process enables 40% reduction in the number of parts manufactured for project-specific measurements, equating to a saving of $160,000

Total cost-saving benefit, in this one project alone, $288,400

However, this does not take account of the opportunity cost. The opportunity available through validating a process on time (or ideally, early) is usually very significant for a medical device company. In this case study the opportunity for the new product is approximately $1m per month in revenue, following validation – so the 4-month delay in the validation would potentially cost the company $4M!

**A3. Case Study 3 – Cardiovascular device design and FDA submission**

How could best practice materials information management reduce costs and increase profitability due to more efficient design, testing, and regulatory application submission processes?

**Design process**

We assumed an OEM senior Design Engineer earning $100K per annum with 135% fixed overhead cost = approximately $140/hour.

We further assumed time spent looking for, and through, existing data held in separate PC-based filing systems and hard copy for a new design iteration amounts to 1 hour per day each working day of the year (likely to be split between several design engineers in a department). Time spent specifying and discussing new test data and test requirements (including test protocols) with other staff was taken as 3 hours per day for each working day of the year (again, likely to be split between several design engineers in a department). With these assumptions the total cost per year spent on data requirements for new product design is $117,500.

If an effective materials data archiving and management database system reduces this time by just 40% then a saving of $47,000 can be realized.

**Testing time**

We assumed:

- Skilled operator = $26/hr + 135% fixed overhead
- New Product Development staff engineer = $53/hr + 135% overhead
- New Product Development principal engineer = $67/hr + 135% overhead
- Time spent on testing material properties for due diligence during design and submission process is equivalent to three full time operators in new product development (NPD) = $307,900 per year.
- Time spent on new data generation and analysis, historical comparison, simulation correlation and report compilation for NPD amounts to one full time staff engineer (likely to be split between several staff engineers in a department) and one full time principal engineer (again, this is likely to be split between several staff engineers within the department), a total of $473,800 per year.

A good materials data management system could at least halve the time required for the whole testing and validation process – particularly as new products are often next generation products based upon existing devices and materials, from which data could be used and lessons learned if the information were readily available. Halving the testing and analysis resources and associated labor overheads in this example would equate to a saving of $391,000.

**Submission date**

Let us assume that the combined effect of the above use of best practice materials data management results in the new product being released 4 weeks earlier than would otherwise have been the case. For a significant new product from a large OEM expected to make $50 M p.a. revenue and assuming a 70% gross margin, the OEM could expect an additional return of well over $2.5million in the first year!
Appendix B – Materials Data Recommended for an FDA Submission

B1. Stress history recommendations from FDA guidance document (for stents)

Stress History

FDA recommends that you include the entire stress history of the device in each loading step. The entire stress history may include, but is not limited to:

• initial fabrication
• expansion
• loading onto the delivery system
• deployment
• physiologic loading conditions.

If you believe that you do not need to model the entire stress history, we recommend that you use material properties that are consistent with the starting point of your analysis. We recommend that the material properties accurately reflect the processing history of the stent as described in 7. Mechanical Properties. We also recommend that you explain why the omitted loading steps either do not affect the stent fatigue life or are accounted for in your model.

B2. Information to include in test reports from FDA guidance document (for stents)

What information should sponsors include in test reports?

Your test reports should include the sections described below.

Test Specimen Information

Your test specimen description should include:

• number of test specimens
• size (diameter, length, or other relevant dimensions) of all test specimens
• rationale for the number of test specimens and sizes tested
• whether the specimens are representative of the finished product
• sterilization parameters and number of sterilization cycles applied to the test specimens

Test Protocol

You should submit your test method or protocol. It should contain enough detail that an individual familiar with intravascular stent testing will be able to interpret the test results.

Protocol Deviations

You should describe any protocol deviations and their effect on the ability of the test data to support the safety and effectiveness of the device.

Test Parameters and Acceptance Criteria

You should report the test parameters and acceptance criteria that you use, including:

• an explanation of and rationale for critical test parameters
• specifications or acceptance and rejection criteria
• a rationale for the specification or acceptance and rejection criteria based on the clinical requirements of the device.

Raw Data

We recommend that you include all raw data in appendices or on a CD-ROM, or make the raw data available for our review upon request.

Test Results

You should summarize your test results and include statistical analysis when it is appropriate.

Data Analysis

You should analyze the data, including any outlying points and anomalous results, and explain whether the data meet the given acceptance criteria.

Conclusions

We recommend that you describe the conclusions drawn from the test results, and the clinical significance of the conclusions.