


<p><b>Personal Profile</b></p>	 <p><b>William (Bill) Jameson</b>  wjameson@accesscomm.ca  (732) 299-7449 mobile  (306) 949-5531 land line  (306) 949-1552 fax</p>
<p><b>Selected Examples of Results</b></p>	<ul style="list-style-type: none"> <li>• Managed a multidisciplinary team of scientific, process, QA, and project resources for a \$4billion combination drug/device product, transitioning new and improved manufacturing processes into production over a period of 2 years. These changes significantly improved reliability and enabled an 8-fold improvement in a crucial label claim.</li> <li>• A comprehensive review of design, service, production, and quality aspects of a troubled in-vitro blood diagnostics system led to a prioritized portfolio of corrective action programs. Successful delivery resulted in a tenfold reduction in end user complaints, field service calls, and corrective actions.</li> <li>• Set up and managed a complex program to combine dozens of similar biologics research products into a restructured production sequence, consolidating operations and IT systems that resulted in \$10million annual savings and enabled a ten-fold increase in new product line introductions.</li> </ul>
<p><b>Summary of Experience</b></p>	<p>A well-respected technical and program manager, with over 35 years experience in both commercial and consulting environments. Diverse background offers a deep, transferrable understanding of what causes programs to succeed or fail, and what to do about it.</p> <p>Manufacturing industry focus, with specific expertise in the mechanical and medical device sectors. Dedicated to commercializing and improving product designs and production processes through a collaborative approach dedicated to risk identification and solid program management. Consistently delivers more accurate, reliable, and profitable products, processes, and operations.</p> <p><b>Managing complex product/process implementation programs</b></p> <ul style="list-style-type: none"> <li>• Program Office management of multiple work streams. Consistent success in identifying and managing risks to ensure reliable delivery.</li> <li>• Highly experienced in managing multidisciplinary and/or matrix-based implementation teams within a milestone-based program structure.</li> <li>• Effectively develops communication and management plans, building agreement across the organization while adapting to changing business influences.</li> </ul> <p><b>Manufacturing Readiness of medical devices and commercial products</b></p> <ul style="list-style-type: none"> <li>• Bridging the transition between R&amp;D and commercial production, ensuring that V&amp;V and process capability issues are firmly resolved in advance and all aspects of manufacturing readiness have been addressed.</li> <li>• Implementation focused, driven to deliver improved performance.</li> <li>• Assessment and realignment/restructuring technology and manufacturing processes. Developing and implementing achievable plans to support mergers, acquisitions, or consolidation of operations and supply chains.</li> </ul>

## Track Record – Example Case Studies

### **Managing commercialization of a redesigned production process**

A series of crucial new process technologies were slated for an existing multi-billion dollar combination medical device, but process throughput and quality could not be compromised or market share would evaporate.

Managed the team of technology, manufacturing, and program resources:

- Process revisions were confirmed to be capable before implementation
- Comprehensive program plans were developed and a management process established for implementation
- Supply Chain, Quality, and Regulatory issues were identified and resolved.

Improvements enabled an 8-fold improvement in a crucial label claim, preventing competitive erosion of the product's dominant market share.

### **Consolidating similar medical devices into a single production facility**

Two similar product lines for mechanical heart valves needed to be consolidated at a single site to reduce costs. Managed the comprehensive assessment of production technologies, engineering know-how, quality and regulatory requirements, production skills, transfer costs, and coordinated development of the financial model.

This enabled a decision on which facility to retain. Working closely with senior staff from both sites, a management plan was developed. It provided comprehensive details of the product, process, and knowledge transfer, regulatory strategy, recruitment and redundancies, and financial investment required to achieve a post-integration €5million annual cost savings.

### **Combining multiple research biologics products into a single facility**

Dozens of legacy product lines existed, each with its own production flow, process, and IT system. This had crippled production efficiency and the speed of introducing new products.

Managed the joint client/consulting team to restructure the production process workflows, taking advantage of common sequences and new shop floor scheduling logic to enhance throughput and mix flexibility.

New IT systems also were needed to support the streamlined processes. Software suppliers were identified that could best support the new URS. Final selection and implementation plans for a unified MES system were developed to support both current and future needs of the business.

The restructuring offered a \$10million annual savings and enabled a ten-fold increase in the introduction of new product lines.

### **Addressing product reliability issues in a clinical imaging system**

Conducted a focused review of possible subsystem failure modes, drawing information from R&D, engineering resources and formal FMEA analyses to arrive at a prioritized list of probable reliability issues, frequencies, and anticipated consequences.

Detailed prioritization and comprehensive program plans were developed interactively with client resources to make corrections and sidestep the field-service and client-satisfaction consequences.

The system now dominates the market and enjoys a solid reputation for reliability and performance; continuing to return huge profits for the client.

## Track Record – Example Case Studies (*continued*)

### **End-stage program management for a medical implantable**

Production and regulatory issues threatened to sink a newly-introduced drug/device combination product. A project office was established and detailed project plans were developed to address both immediate and critical long-term issues related to:

- Severe production shortfalls due to process inconsistency
- QSR compliance issues that threatened to shut down operations
- Supply chain incapability for key components
- Dramatically low finished-goods yields

The integrated program brought together regulatory, quality assurance, product and process engineering, production, planning, and resource management functions to launch a series of clearly defined successful improvement initiatives

### **Predicting failure modes for a surgical instrument**

Managed the program to determine if unforeseen failure modes were most likely in a redesigned precision electromechanical surgical device.

An effective Failure Mode and Effect Analysis led to an extremely novel accelerated automated lifecycle testing process that alternated accurately simulated tissue cutting with autoclave sterilization. Early failures began to emerge, which enabled rapid corrective design changes.

The 2 month program successfully helped the client avoid a major product recall that would have irreparably damaged product line credibility.

### **Concurrent product/process design for a movable manufacturing site**

A high-precision commercial-scale solar energy product needed to be manufactured in high volumes at the installation site, but design requirements were unclear and the proposed production processes were incapable of achieving the required tolerances or production rates.

User Requirements and Design Specifications were finalized, and unrecognized failure modes were identified and addressed by rapid design iterations. Parallel activities focused on developing an innovative, capable production process that could be replicated to support global installations.

Detailed and achievable program plans included structured verification & validation activities to ensure that implementation risks were minimized

### **Recovery plans for a failing production consolidation**

An entire global business unit was being re-established at a single production facility, with several facilities scheduled for shutdown. Communication from the redundant facilities was poor, and supply chain, staffing and IT issues threatened the viability of the transfer.

An intense 2-week assessment gathered information from virtually all aspects of the business, prioritized the root causes implementation failures, and set out detailed actions and responsibilities to correct them.

A final decision workshop solidified management commitment to the recovery plan and re-launched the implementation program.

## Track Record – Example Case Studies (*continued*)

### **Improving the effectiveness of a drug discovery process**

Used computerized simulation tools to model a major international pharmaceutical client's drug discovery process. The model was carefully developed to identify not only the key process steps, but possible sources of bottlenecks, overlaps, delays, rework, and sources of variability. The model was confirmed against real-time experience to verify its applicability.

Used the model to interactively explore the effect of possible changes with both Managers and Scientists, and developed a three-year plan of investment in facilities and technology that targeted a 20-fold increase in throughput.

### **Feasibility assessment of stent manufacturing process technology**

Technical challenges had stalled final commercialization of an advanced cardiac stent manufacturing technology. Bill led a detailed assessment of the pilot production facility, optical/chemical manufacturing processes, and quality/inspection methods. This data was mapped against the product requirements to identify any gaps in the process capabilities.

The evidence and analyses confirmed that the process was incapable of ever meeting commercial-scale manufacturability expectations, and was terminated to avoid further investment losses.

### **Pre-merger technical due diligence of two equipment manufacturers**

Managed a jointly commissioned assessment to clarify on which organizations and products should be retained after a proposed merger between two blood-processing multinationals.

Multi-site interviews and a review of selected data were used in assessing the performance and reliability of each manufacturer's products, business processes, manufacturing capabilities, NPD pipeline, and staff.

Recommendations clarified which portions of each company should be retained, and details of how they could be combined most effectively to ensure market domination. This provided a guidance framework for the implementation team and laid the groundwork for the Program Office.

### **Correcting reliability problems for a diagnostic machine**

Conducted a detailed, multidisciplinary, reliability audit of a troubled in-vitro blood diagnostic system, combining:

- Analysis of historical information, technical data, and end-user interviews
- Structured subsystem performance testing,
- Comprehensive reviews of production operations, design methods, service methods, and quality processes,
- Product & Process FMEAs, with both client and consulting resources

...to create an inventory of subsystem redesign and field service initiatives.

A final multi-day client session agreed a time-based portfolio of projects to achieve a tenfold reduction in customer complaints.

### **Identifying and reducing manufacturing process risk**

A novel device for semiautomatic deployment of radioactive iodine brachytherapy seeds had been developed, but the consumable for loading and placement was inconsistent and costly to manufacture. A detailed review generated revisions in both the product and process design to achieve a 3-fold increase in throughput and a dramatic increase in product quality.

<b>Additional Background and Credentials</b>		
<b>Partial list of Medical Device and Commercial Clients</b>	3M Applied Biosystems Baxter Healthcare Bayer Diagnostics/Siemens Behring Diagnostics Cytyc Dako Cytomation Johnson & Johnson companies	MicroDose Therapeutx Nycomed Pfizer Roche Diagnostics Sanofi Winthrop Pharmaceuticals Smith and Nephew Sorin Biomedica Warner Lambert Pharmaceuticals
<b>Background and Qualifications</b>	<p><b>Managing Consultant</b> – PA Consulting Group, Princeton, NJ            Large international technology and management consulting firm            Technology and Healthcare Practice            1992-1998 and 2001-2009</p> <p><b>Partner</b> – Management consulting firm specializing in organizational and program management effectiveness</p> <p><b>Director of new technology development</b> – medical device startup</p> <p><b>Senior NPD project manager</b> – regulated consumer products</p> <p><b>Other responsibilities:</b></p> <ul style="list-style-type: none"> <li>Manager of new product development</li> <li>NPD program manager</li> <li>Director of manufacturing engineering</li> <li>Director of Quality Assurance</li> <li>Project and production management</li> </ul> <p><b>Degreed Engineer</b> – Lehigh University, Bethlehem, PA</p>	