

Experience
Expertise
Results



Presentation at



Future Medical Manufacturing Forum

March 27, 2006

"Giving commercial value to the brilliant ideas of others"

Thomas Alva Edison

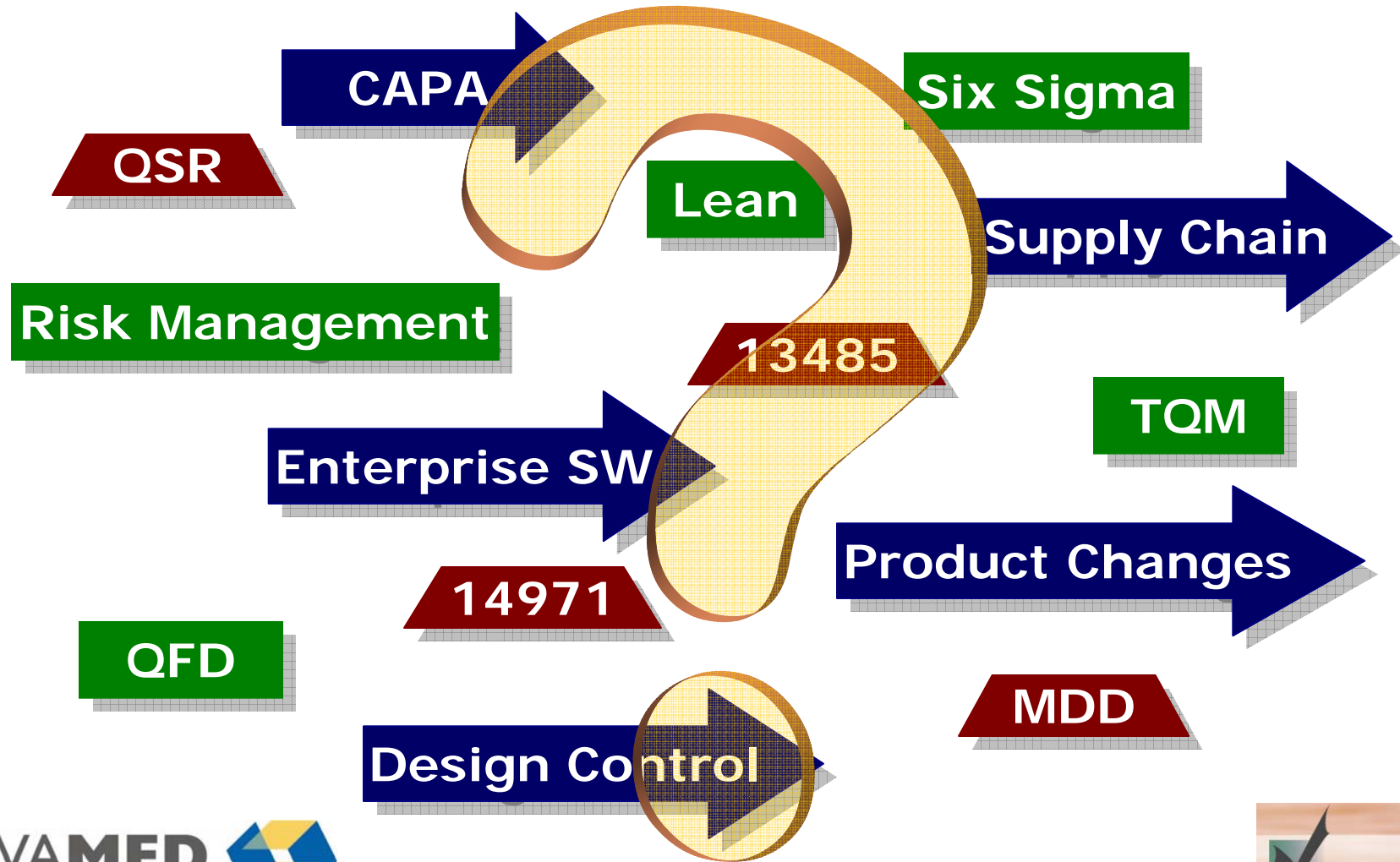
Today's hot topics...

**management
techniques**

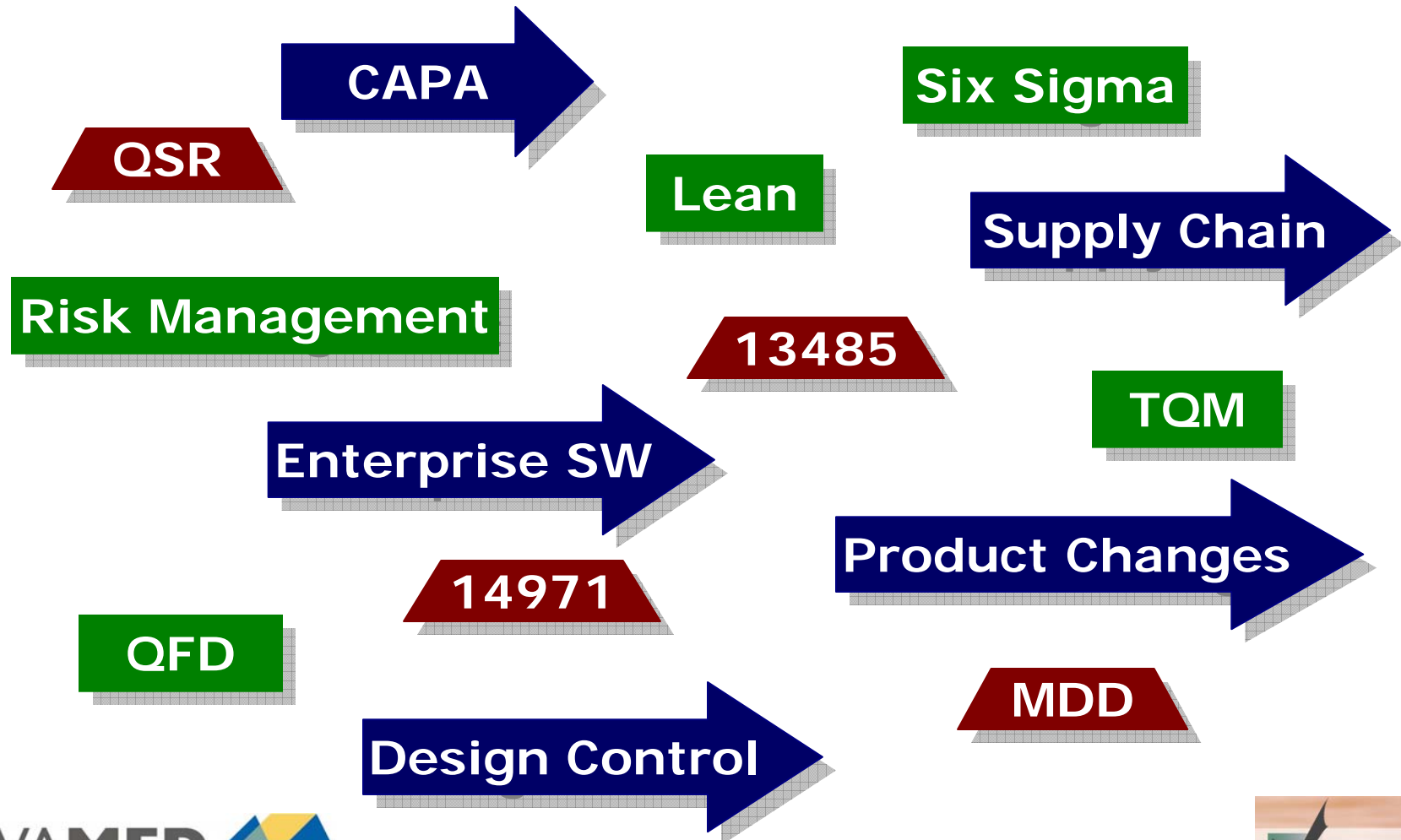
regulations

**operations
&
processes**

What do they have in common...



Getting the Right Product to the Customer



Getting the Right Product to the Customer

- How does one navigate this challenging environment?



- A fundamental approach is to understand...
 - Who the customer is
 - What the right product for that customer is
 - What their primary concern in getting it is

The Customer

The Right Product

Key Drivers



User/Patient →

✓ Function
✓ Performance



Requirements;
V&V

Purchaser →

↓ Cost \$



Requirements;
DFM

Company →

↑ Profit \$



Risk management;
Efficient DCP

R&D-Eng. →

Elegant design



Requirements;
Design review

Production →

↓ Difficulty



DFM;
Mfg on dev. team

Regulators →

✓ Safe ✓ Effective
✓ Meets intended use



RA/QA
Expertise



Design Control Process

- Efficient & Robust
- Document templates
- Early manufacturing involvement critical
- Benefits from dedicated project management
- Difficult to maintain design control in a deep supply chain
- Must be integrated with the post-release change process





Requirements Engineering

- The foundation for design efforts
- An important engineering discipline
- Requires training & practice to gain skill
- Requires sufficient time & resources
- Requires adequate customer input
- Best when started early
- Control of requirements with outsourced design is particularly challenging





Design for Manufacturing

- Development engineers often do not have much manufacturing expertise
- Manufacturing engineers often do not have much development expertise
- Engineers with significant development and manufacturing experience can bridge the gap
- Early manufacturing involvement in the development process is essential

Case Study: Design Control / Requirements

- **Challenge:** Client was developing a new imaging system and was concerned that design verification would be less than optimal due to requirements developed by separate contractors
- **Solution:** AlvaMed supplied a team experienced in requirements who reviewed and thoroughly analyzed the various requirements documents
- **Results:** The team quickly identified duplicative, inconsistent, ambiguous, and missing requirements





Risk Management

- More comprehensive than hazard or failure modes & effects analysis
- Needs to cover all aspects of the entire product lifecycle
- Difficult to implement when resources are constrained
- Ultimately improves profitability
—an investment rather than a cost





Design Verification and Validation: V&V

- Verification is more than testing...
 - Inspection & analysis
- Efficiency of V&V...
 - Lowers cost and shortens time to market
- Design failure modes & effects criticality analysis (dFMECA)...
 - Underutilized as a tool for planning an efficient V&V program





Manufacturing Process Optimization

- Lean principles can be used to increase efficiency by reducing waste
- Process failure modes & effects criticality analysis (pFMECA)...
 - Underutilized as a tool for reducing the amount of inspection and testing required





Quality and Regulatory



- Quality throughout the organization is an essential component of regulatory compliance



- Major issues arising on FDA 483s...
 - CAPA: Insufficient resources, inadequate systems
 - Internal Audit: Insufficient resources
 - Production Controls: Process validation
 - Design Controls: Change management

Case Study: Design Control / Regulatory Response

- **Challenge:** Client was unable to adequately respond to an MDR reportable event which occurred on a vascular device following a change made without sufficient design control
- **Solution:** AlvaMed created an improved design control system, then led a team which generated the missing design control elements
- **Results:** The resulting DHF enabled the company to adequately respond to FDA





Sufficient Resources— quantity and expertise

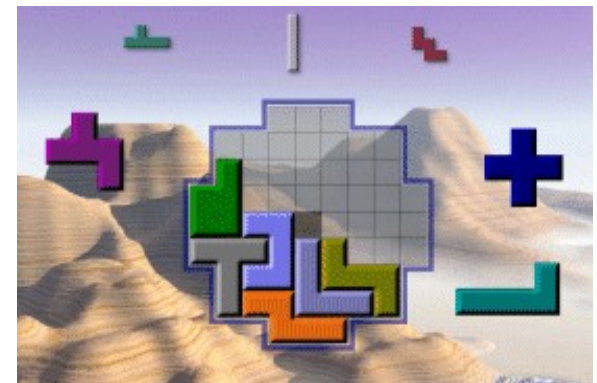
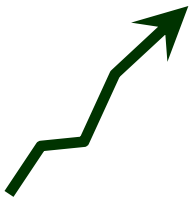


- Most organizations are resource constrained
- Even with adequate staffing, some expertise may not be needed on a full-time basis
- Delaying a new product introduction by even a few months can decrease the NPV of the future revenue stream by millions of dollars

AlvaMed Can Help

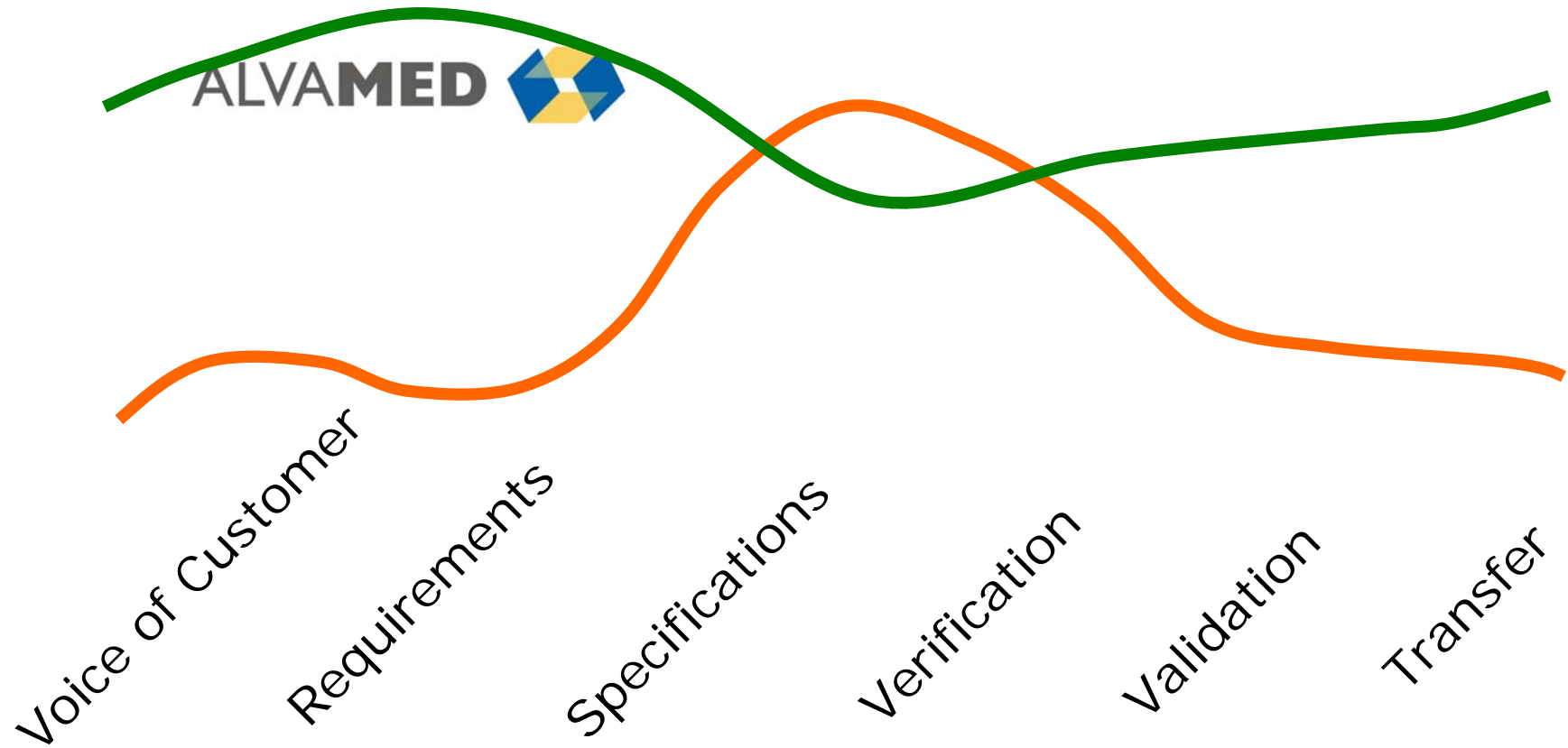


- AlvaMed delivers creative and practical solutions in all these key impact areas
- Exclusively dedicated to the medical technology industry
- Founded in 2003 and growing steadily
- Our consultants have the cross-functional expertise to effectively solve challenges in a regulated environment





Core Competencies

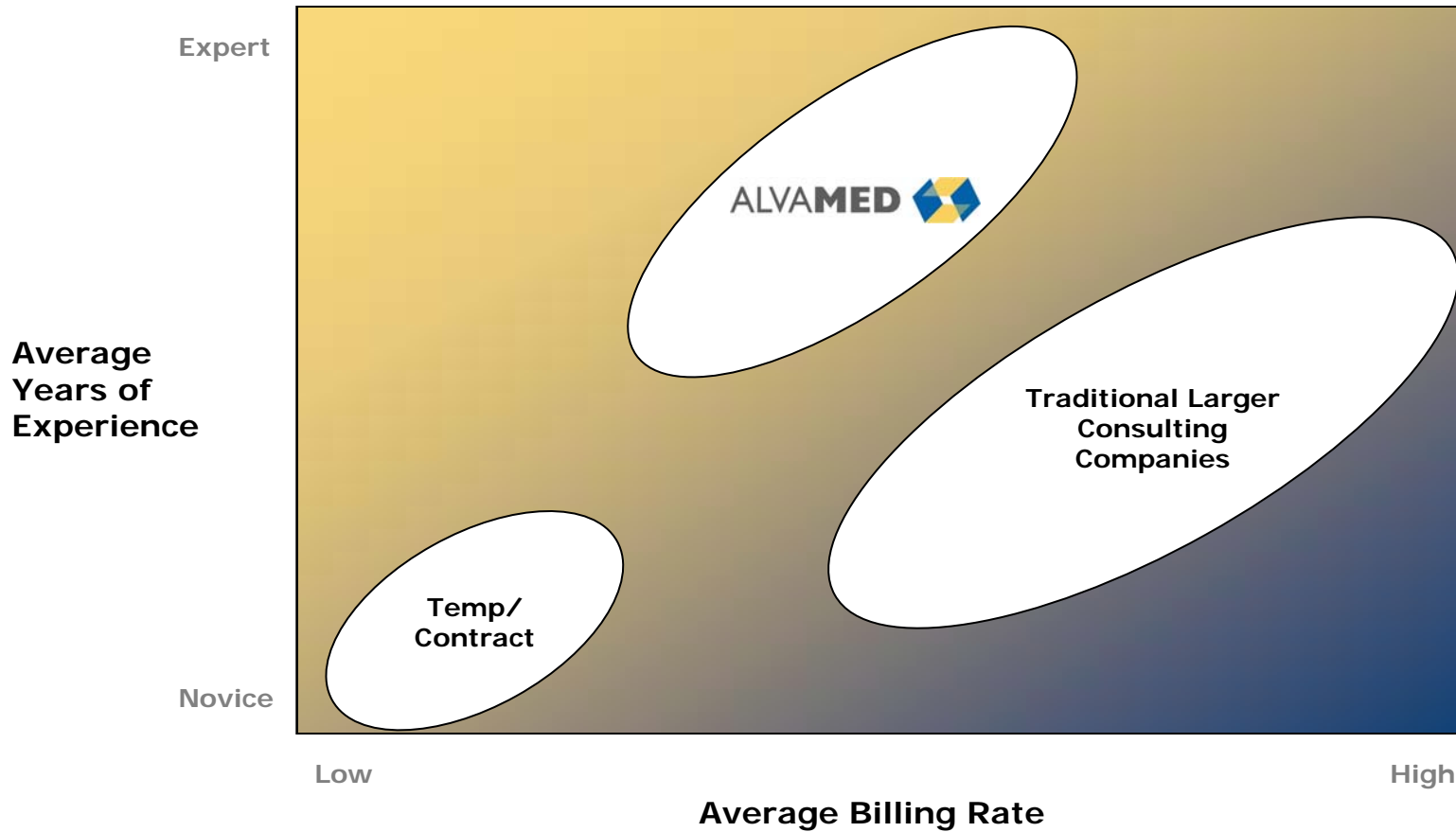


Outstanding service to clients

- Our people set us apart...
 - Depth of expertise and experience
 - Multi-disciplined
 - Industry trained
- We work according to your needs...
 - On site or off
 - Integrated with your team or independently



Compare us with other consulting choices



Challenges

- Today's big issues, although...
 - Complex
 - Interrelated
 - Challenging
- Have common themes...
 - that can be used to analyze the key impactors
 - and develop effective solutions

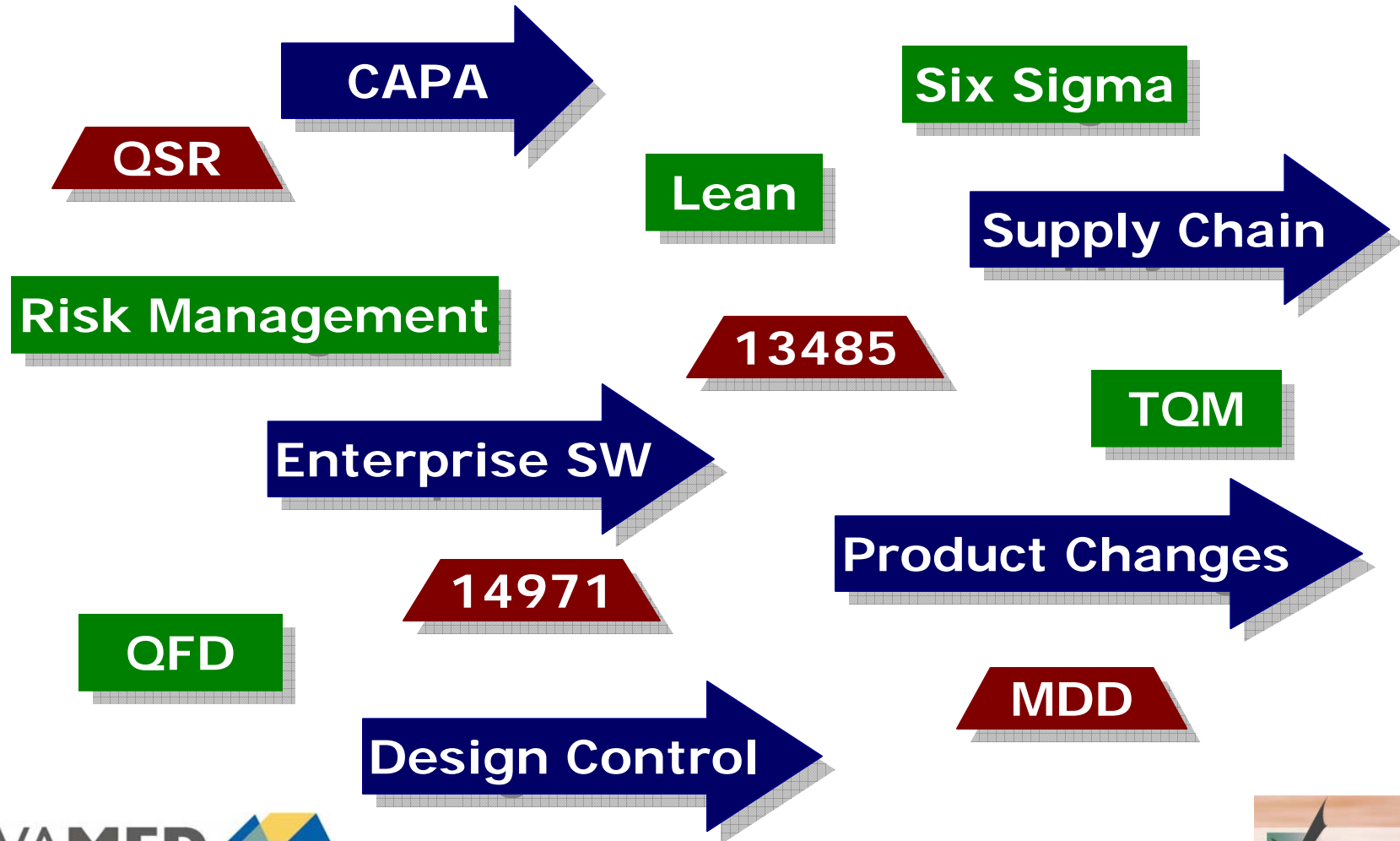


Solutions

- Whatever...
 - Operational or process problems exist
 - Management techniques are in use
 - Regulatory hurdles need to be overcome
- AlvaMed can supply solutions that are...
 - Effective
 - Practical
 - Have a high return on investment



Let us help you get from here...



To here...

