

FDA's Pharmaceutical Quality Initiatives – Implementation of a Modern Risk-based Approach
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**Breakout Session J:
Implementation of Quality Risk Management**

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How QRM Tools are Being Used

- Design of facilities
- As a communication tool in everyday decision making
- Examples: Fishbone, FMEA, FMECA
- Training schedules
- Development
- Identification of critical parameters
- QRM to Assess Quality Systems
- Parametric Release

“Good” vs. “Bad” QRM?

- Proactive vs. Reactive
- Multi-disciplinary groups/activities
- Objective facilitator
- Need integrated approach
- Can't be used to justify a bad decision
- Iterative not static
- Learn from device industry

Integration of QRM in PQS

- QRM is already an accepted concept
- Should be integrated part of PQS, not independent
- Integrate into change management systems, recalls and deviations
- Development and manufacturing need to communicate and share:
 - “break down silos”

Application and Training

- Regulatory training is happening
- Need for real-world learning examples
- ICH Website “Briefing Pack”
 - <http://ich.org>
- PIC/S Training for regulators
- *Practical* pharmaceutical industry training

Remaining Challenges

- Start-up resources and resources in general
- Information gathering and knowledge management
- Which tool to use?
- Transparency of risk management between regulators and industry
- Legislation constraints
- Too many new initiatives?

Recommendations

- Communication
- Common Sense
- Cultural Change
- Common learning
- Commence!