

Implementation of a Pharmaceutical Quality Assessment System: Challenges, Progress and Opportunities

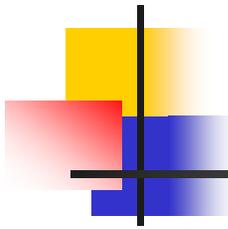
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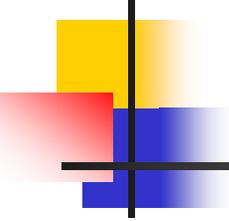
Vision for the Future

- Janet Woodcock, FDA (Oct 2005)
on the Desired State:
“A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight”



Foundation for Future

- Establish framework for a modern approach to pharmaceutical quality and manufacturing
- Emphasize manufacturing science, risk-based assessment, robust Quality Systems
- Encourage thorough understanding of process and product
- Emphasize what is critical
- Endorse continuous improvement over a product's lifecycle



Pharmaceutical Quality Assessment System Initiative

■ Challenges

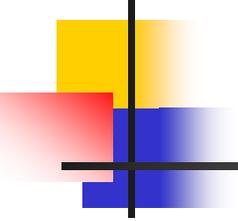
- Driving and embracing significant change
- Moving to very different paradigm impacting pharmaceutical development, review and assessment, submission content, post-approval environment
- Strategic vision ensuring alignment of all the moving parts

■ Progress

- Certain areas have forward momentum
- Other areas are still in conceptual phase

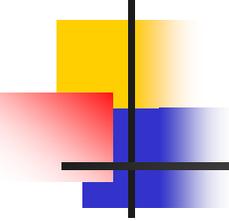
■ Opportunities

- Many – some defined, some yet to be defined



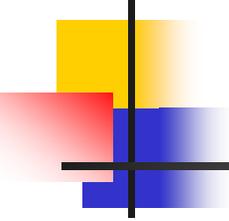
PQAS: FDA/Sponsor Interactions

- Challenge: Changing FDA/Sponsor interactions
 - More frequent, different interactions
 - Adequate expertise, time, and resources
- Progress:
 - More CMC-only meetings
 - Interactions have increased for Pilot Program experiences
- Opportunities:
 - Continue progress beyond Pilot Program
 - Determine the right venue, frequency, and participants



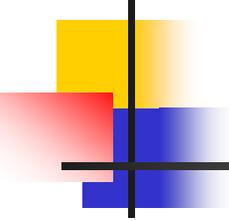
PQAS: Submission Content

- Challenge: Submission content will be different
 - Conveying Quality-by-Design knowledge
 - Current contents of Module 3
 - Role of Module 2 (QOS)
- Progress
 - Several Conferences and Workshops
 - EFPIA Mock P2 and Pilot Program experiences
 - Future ICH opportunities – Q8B, QOS
- Opportunities
 - Continued public discussion
 - Closer examination of Module 2 and Module 3
 - Elimination of non-value added information, redundancy
 - Global acceptance



PQAS: Assessment and Approval

- Challenge: Assessment process, focus, and approval will be different
 - Readiness of reviewers
 - Impact of sharing more knowledge
 - Achieving Quality by Design
 - Role of the Regulatory Agreement
 - Integrate non-QbD activity
 - Role of inspectors
- Progress
 - Changes in FDA organizational structure and review process
 - Pilot Program experiences
- Opportunities
 - Continued implementation of review process changes
 - Move concept of Regulatory Agreement into practice



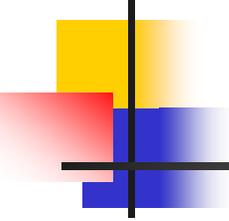
PQAS: Rethinking Concepts

- Challenge: Concepts will change
 - Quality by Design and Design Space
 - Specifications
 - Validation
 - Regulatory commitments
- Progress
 - Discussion has begun in public meetings
 - March 2005 Specifications Workshop
 - October 2005 PQAS Workshop
- Opportunities
 - Continued discussion and clear alignment on all of the above
 - Global acceptance where feasible

PQAS:

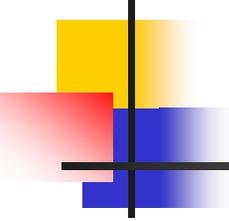
Post-approval Environment

- Challenge: Post-Approval environment will change
 - Defining and achieving regulatory flexibility
 - Handling of post-approval changes
 - Evolving Quality Systems
 - Ensuring continuous improvement
 - Clear roles of Center and Field
- Progress
 - Potential role of Regulatory Agreement discussed
 - ICH Q8, Q9, Q10
- Opportunities
 - Move concept of Regulatory Agreement into practice
 - Determine specifics of new post-approval environment



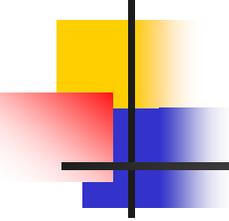
PQAS: Center vs. Field

- Challenge: Understanding roles and responsibilities of the Center vs. Field
 - Identifying responsibilities and accountability
 - Engagement at appropriate time, frequency
- Progress
 - Identified as a topic needing discussion
- Opportunities
 - Understand specific roles



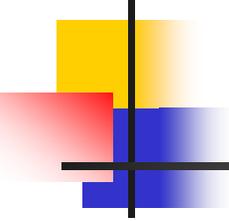
PQAS: Regulatory Guidances

- Challenge: Regulatory Guidances
 - Understanding industry/FDA needs and wants
 - Addressing differing needs across industry
 - Current and future state - co-exist?
- Progress
 - ICH Q8, Q9, Q10
 - Withdrawal of FDA guidances
- Opportunities
 - Global guidances where possible
 - Potential new, different FDA guidances



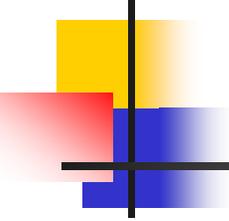
Overcoming the Hurdles

- Ensuring a strategic vision where all the pieces fit
- Working out the details
- We are all at a different place
- Achieving Trust
 - Regulators of industry
 - Industry of regulators



PQAS Success

- To achieve success, we will need to begin or continue progress on defining:
 - Effective communication between FDA/sponsor
 - Understanding Quality by Design
 - Impact on submission content and assessment
 - Regulatory Agreement
 - Post-approval regulatory environment
 - Roles of Center and Field



Conclusion

- We have made some progress
- We still have work to do to accomplish the desired state
- With a strategic vision, focus, and progress on the details we can achieve:
 - “A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight” J. Woodcock