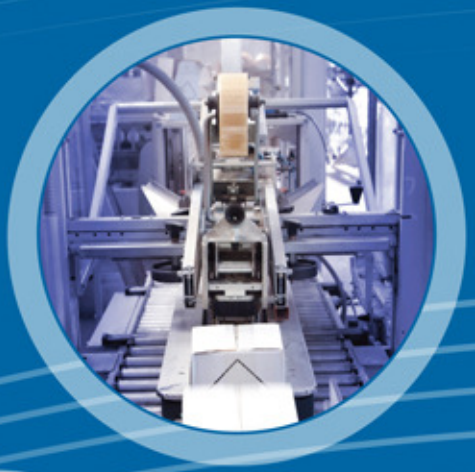
Connecting People, Science and Regulation®

# Closing Remarks

**David Tainsh, GSK**
**Keith Pugh, MHRA**



Joint Regulators/Industry QbD Workshop
28-29 January 2014 London, UK

# Reflections on the Two Days

- Openness of Industry to Share Approved Files and Assessors to Clearly Outline their Thinking
- Very Positive Interaction between Regulators and Industry
- The authenticity of the Case Studies added to the richness of the discussion in the Room
- Meeting was enhanced by the Inclusion of the Biopharm and International viewpoints
- Discussions and Recommendations have Created an Expectation to Follow Through

# Broad Ranging Main Themes

- Design Space
  - Scale-Up and Verification
- Risk Assessment
  - Risk and Criticality
- Control Strategy
- Real-Time Release Testing
- Multivariate Models & MSPC
  - Single and Multiple Unit Operations
- Life Cycle Management
- Submission & Review of QbD Files

# Case Study Findings

- Different Learnings can be taken from all six case studies
  - They weren't all perfect from the start.
  - Everyone has learnt and progressed through doing and having the interaction
- Use of consistent ICH terminology is essential
- Be clear and compelling in setting out the story and "The Ask"
- Many examples of the level of detail required being commensurate with the impact of what you want to achieve
  - Risk Assessments, Models, DoEs, PAT, DSp

  relationship to supporting
  - Screening, RTRT, batch disposition, Control Strategy
- A full description of manufacturing process is required including critical and non-critical aspects
- Risk Assessments need to be comprehensive and plausible – the use of RAG colour coding is useful provided it is supported by detailed definitions

# Next Steps

- All Slides will be made available
- The E-mail address for questions will remain open
  - EMA@PDA.org

- Publication of Main Outcomes from the meeting
- An On-demand Video of proceedings to be made available to participants
- Commitment to consider outcomes as input to an EMA Q&A Document
- Commitment to input recommendations to consultation on Annex 16
- Recommendations from the Workshop to be shared with the ICH Informal Quality Discussion Group
- EMA/EFPIA Steering Team to follow up on Learnings

# Thank -You

- Case Study Teams
- Presenters
- Workshop Attendees
  - Including International Guests from FDA and PMDA
- Colleagues On-line
- Hosts
  - EMA
- Chairs, Organisers & Steering Team
  - PDA, EMA, EFPIA

# Meeting Close

Thank you for your attendance and safe journey home