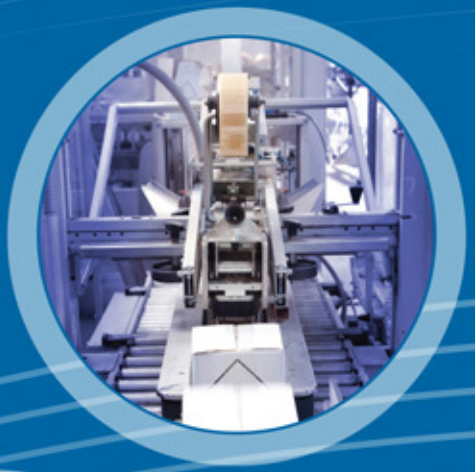
Connecting People, Science and Regulation®

Joint Regulators-Industry Quality by Design Workshop

Introduction and Goals of the Workshop



Georges FRANCE
External Relation Head for quality
Novartis

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

Introduction

- Historical & Learning process
- Initial Intent & Expectation
- From Traditional approach to New Quality Paradigm
- Benefit & Remaining challenges
- Way Forward

"Application including QbD: A Learning process

- March 31st 2008
  - PAT Team visit on real QbD site in Ireland

- Nov 29th 2009
  - EMA EFPIA QbD Workshop

- From 2009 to 2012
  - ICH IWG Implementation support

"Application including QbD: A Learning process (2)

March 31st 2008, Dublin & Cork

EFPIA – EMA PAT Team / QbD Mtg in Facilities in Ireland

- Mock Inspection of development facilities
- Implementation of ICH Q8, Q9 and Q10
- Regulatory Experiences (pilot programs)
- Criticality
- Role of the Qualified Person
- Conclusions
  - Discussion on real life examples was particularly useful
  - Some of the issues are for the regulators to work on, others for industry and some jointly between industry and regulators

- Real Example
- Scientific dialogue

"Application including QbD: A Leaning process (3)

Nov 29th 2009, London

EMA EFPIA - QbD Workshop

- Very positive and open industry (120) and regulators (110)
- General agreement on principles and main discussion focussed on implementation
- Need to continue the dialogue and sharing of examples is key
- Case studies very valuable for further QbD understanding
- More understanding/consensus is highly desirable (both industry and regulators)
- Will be achieved via scientific advice, ongoing dialogue with PAT group, further workshops, amended or new guidance or Q&As (also match new terminology with existing guidelines)

Again !

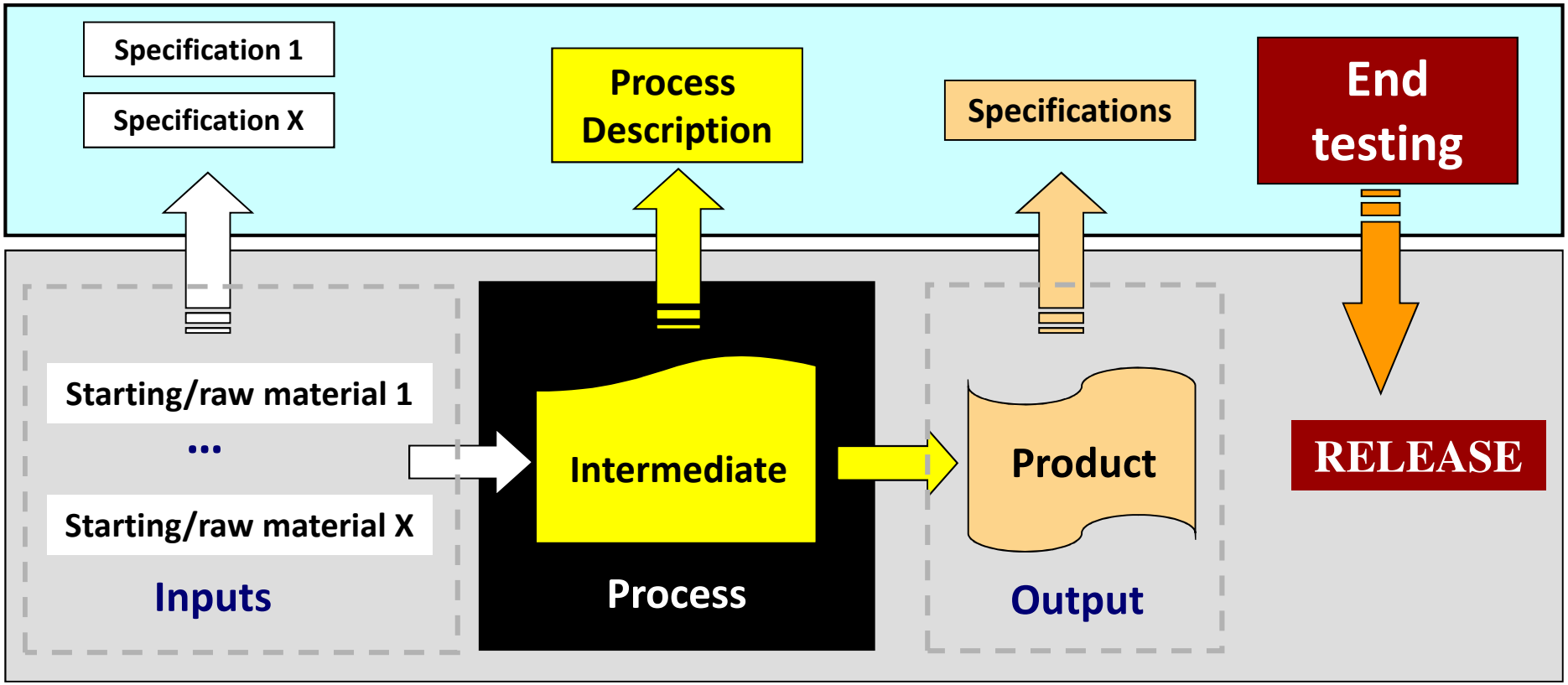
- Real Example
- Scientific dialogue

Industry initial Intent & Expectation

- Facilitate Innovation
  - Benchmarking with other industries demonstrates that there is room for improvement
- Facilitate continual improvement
- Improve trust by sharing more about the development process
- Moving from data review to scientific assessment
- Streamlined Regulatory review
- Considering QRM approach

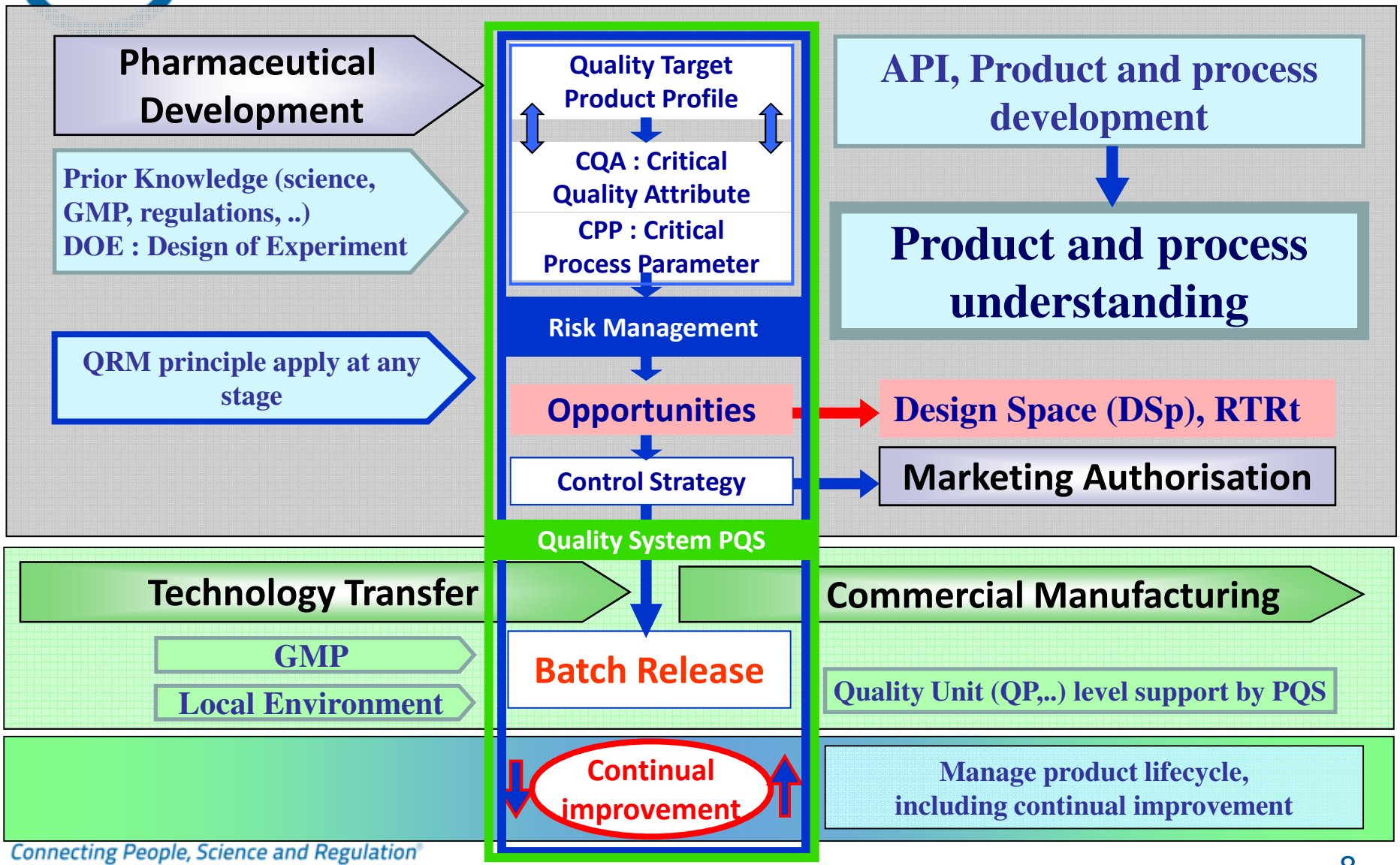
Traditional approach

Traditional / Minimal



QbD "Through Process"

From ICH-IWG Training Package



Benefit for Industry, mainly internal

From Product and Process understanding

- More robust process
- Opportunity to improve yield
- Will reduce Batch failure rate & Minimize number of batch recalls
- Facilitate quality maintenance by a more proactive approach

  - More predictable supply of product
  - Minimise Out of Stock Situation

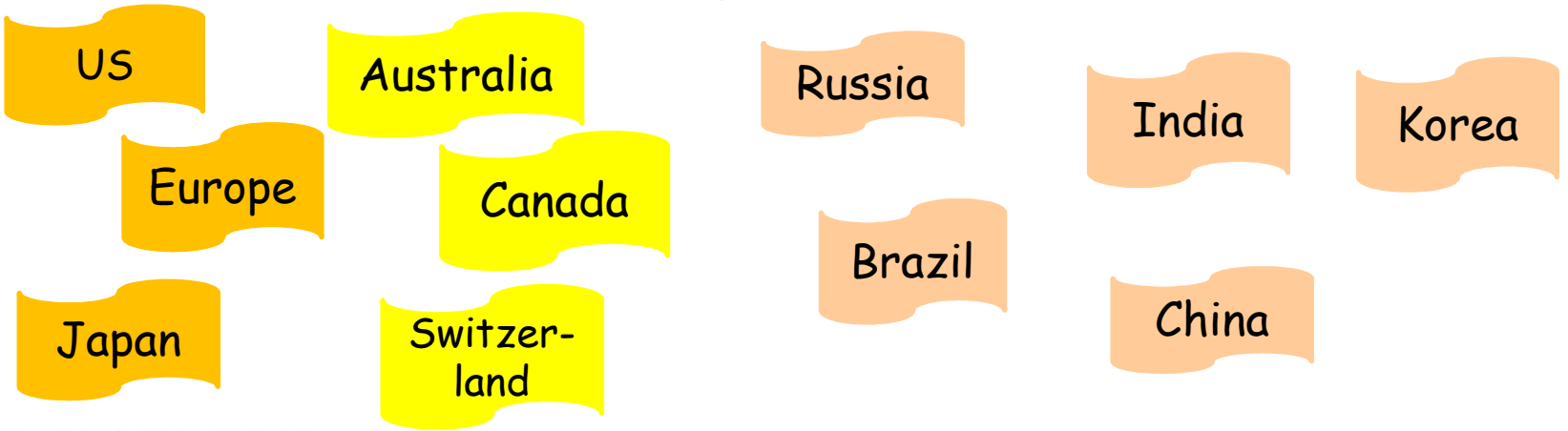
From Opportunities: RTRt and Design Space

- Leads to Continuous Quality Verification
- Will allow Process Monitoring in real time.
- Reduced Batch cycle time
- Reduced final-product testing

  - **Patient** Benefit

Remaining Challenges and way forward

- Associated to the level of information needed & linked to the move from data review to a scientific assessment
  - Quality of the presentation of the file
  - Consistency of the assessment
  - Level of details required
    - Supporting the level of commitment required
    - Supporting the scientific understanding
- ICH alignment (US, EU & Japan) and global alignment



Remaining Challenges and way forward

Step 0-1 Investment

Immediate benefit :

Process understanding

Efficiency & yield improvement

OOS & Recall decrease

Supply Secured

Step 1-2 Learning

Training & pilot

Implementation of Regulatory Trust & harmonisation

Step 3 full Benefit

Trust & predictability

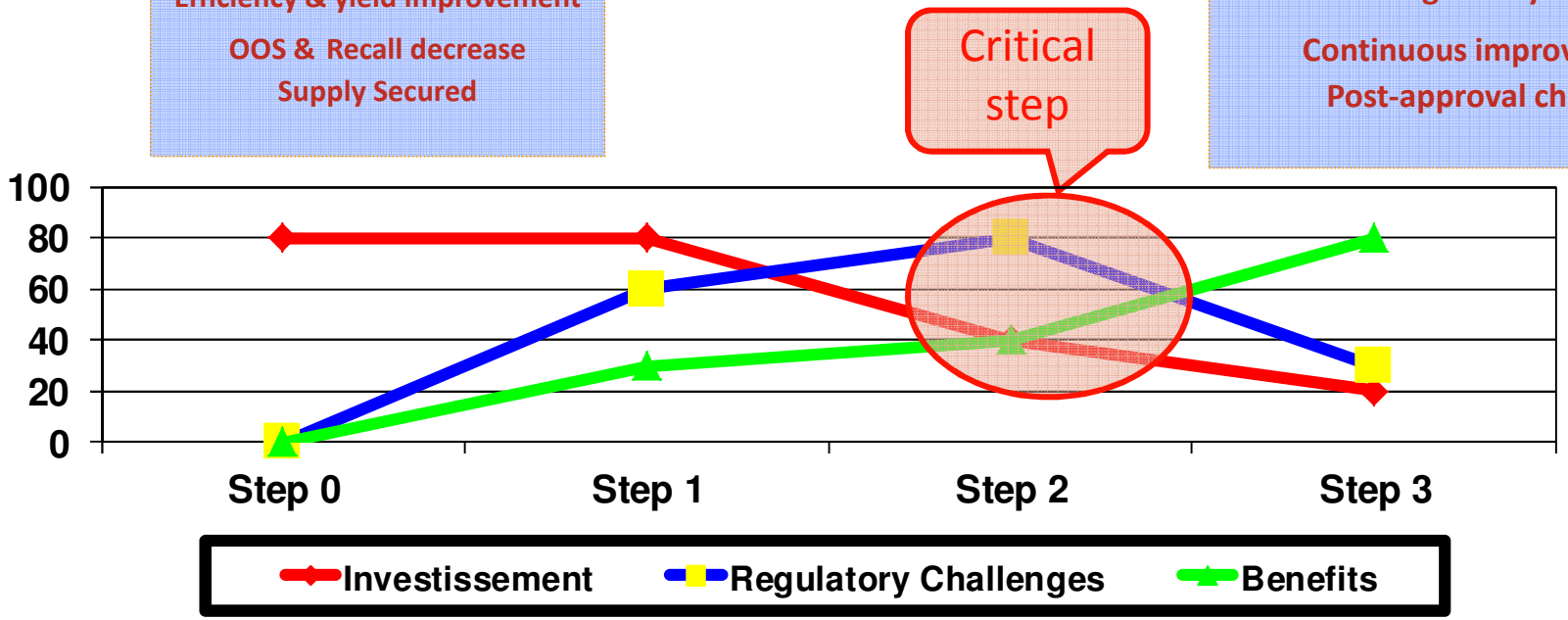
Streamline regulatory review

Regulatory flexibility

Global Regulatory Alignment

Continuous improvement

Post-approval changes



Paradigm Change : A journey

Remaining Challenges and way forward

January 28th & 29th, 2014, London EMA

- A real opportunity to move to “step 3” by improving the common understanding
  - Trust & Predictability
  - Streamlined Regulatory review
  - Global Regulatory alignment
  - Regulatory flexibility (Manufacturing flexibility)
  - Continuous improvement / Post Approval change
- Continue the Scientific dialogue

Tuesday, 28 January 2014

Tuesday, 28 January 2014		
9:00		Welcome, Introduction & Goals of Workshop
9:45	Case N 1	Regulatory CMC Perspective on Quality by Design Dossier Preparations
10:45		Coffee Break
11:15	Case N 2	Design Space Development and Verification
12:15		Lunch Break
13:30	Case N 3	Models to Support Real Time Release Testing: Quantitative and Qualitative Models, and Associated Specifications
14:30	Case N 4	Challenges in the Implementation of Model-Based and PAT-Based RTRT
15:30		Coffee Break
16:00	Case N 5	Control Strategy
17:00		End of Workshop Day 1 & Networking Reception

Wednesday, 29 January 2014

Wednesday, 29 January 2014		
8:30	Case N 6 Panel Discussion	Novo Nordisk Experience in the Application of QbD What is needed to further Implementation of QbD for Biopharmaceuticals?
10:15		Coffee Break
10.45	Questions / Issues from the Audience	Structured Discussion around Common Themes from Case Studies, e.g. : Risk Assessment and Criticality, Design Space, Use of Models, Control Strategy, Lifecycle Management, The Development Story and Presentation of Information in Submissions, Dossier – Quality System Interactions etc…
13:00		Lunch Break
14:00	International Reflections and next steps	Reflections from an International perspective – USA Reflections from an International perspective – Japan Audience discussion – How do we progress?
15:30	Innovation in Medicines and Manufacturing	Future opportunities Closing Summary

What about today and tomorrow

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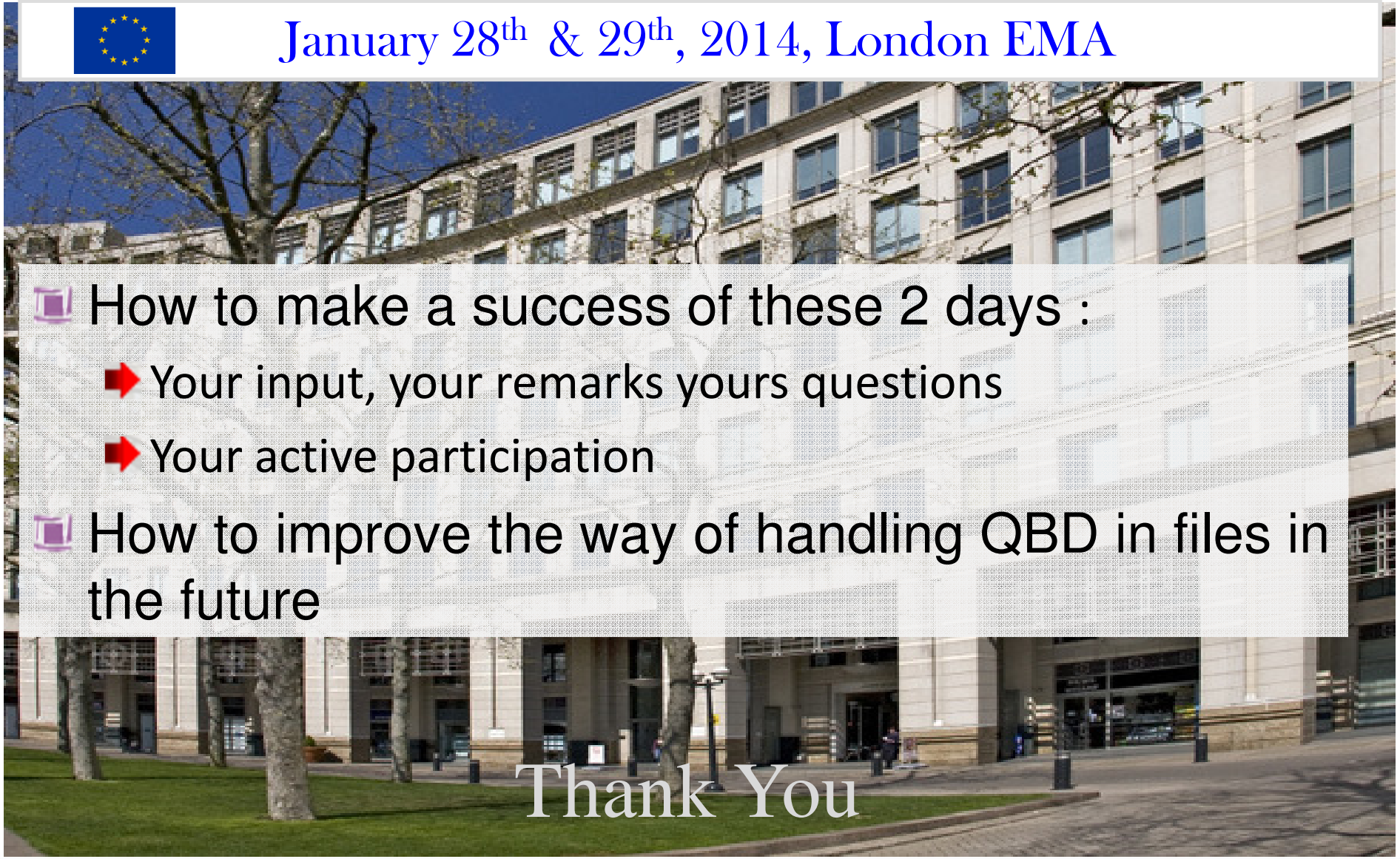

- How to make a success of these 2 days :
  - Your input, your remarks yours questions
  - Your active participation
- How to improve the way of handling QBD in files in the future

Thank You