



INTRODUCTION

Keith Pugh - MHRA, PAT TEAM

With the other members of the EMEA PAT TEAM

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With the other members of the EFPIA steering committee

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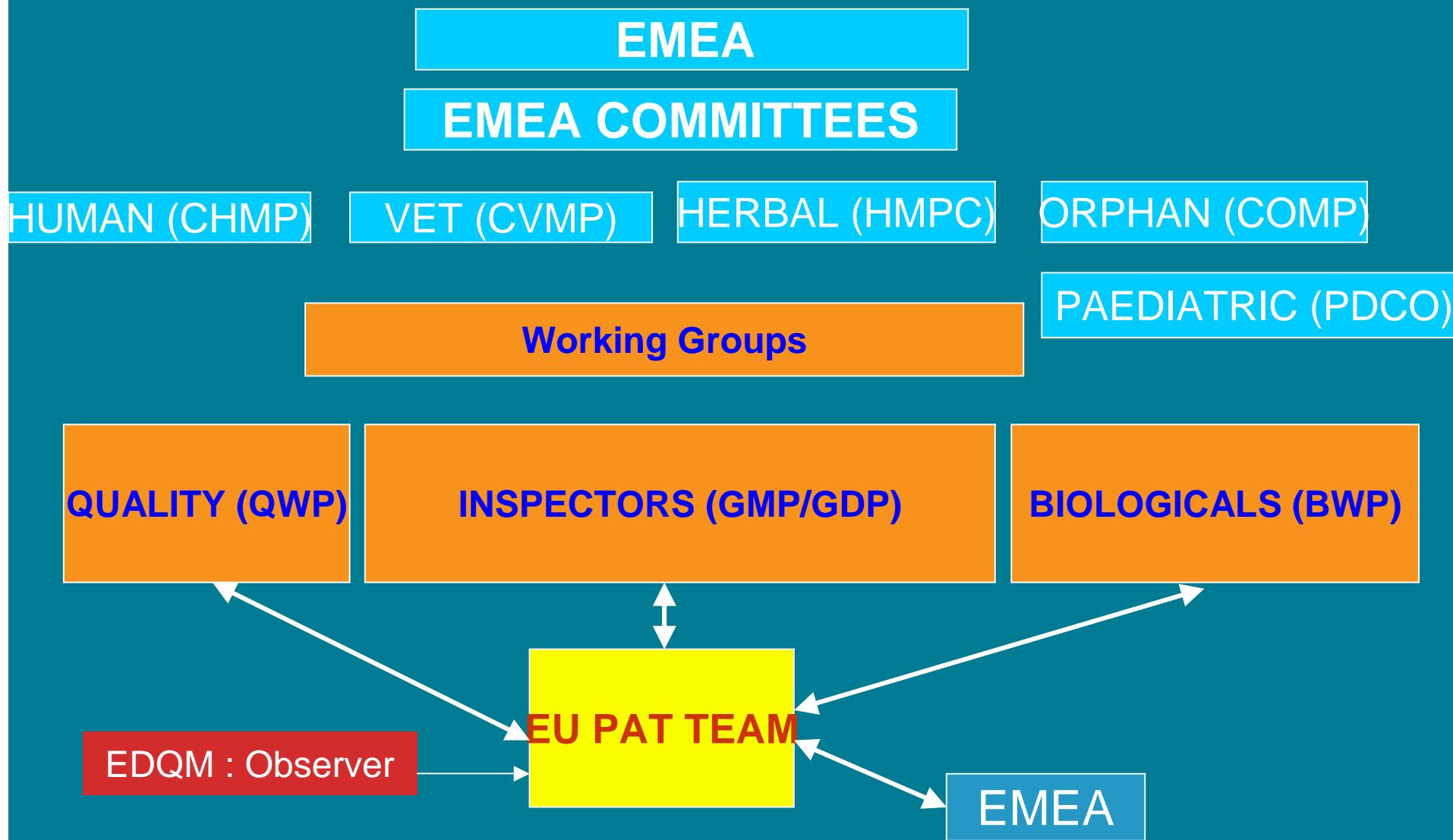
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EU PAT TEAM

- *Mandate:*
(www.emea.europa.eu/Inspections/PAThome)
 - General Objective
 - Specific Objectives
 - Constitution and Organisation

EU PAT TEAM ACTIVITIES - include

- Joint meeting with Biologics working party and Industry (March 2007)
- Seminar with EFPIA in Ireland (March 2008)
- Training/workshop with EFPIA (September 2009)

Implementation of QbD

- A very interesting challenge
- If not a “Revolution” a serious “Evolution”
- A bridge between Development & Manufacturing
- A bridge also between Assessors & Inspectors
- To be valid the science behind QbD needs to be :
 - Readable
 - Based on robust data
- An opportunity, today, to move forward

Objectives of this session

- Follow up of IRELAND Seminar April 08 (Step 1)
- A major opportunity to share “practical example on respective approaches”
- With key regulators from PAT Team, QWP, BWP, IWG
- A need for learning by doing
- A milestone in the way of harmonisation
- Step 2, consideration for Step 3
- Other Initiatives : ICH IWG Training Session (JLR)

Expectations

- A real opportunity from these examples to get Lessons learned
- A Challenging exercise: “LIVE”
- Try to identify
 - Key topics
 - Common approach
 - Points for discussion
- Your input is critical: please be Interactive

DIALOGUE

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