

Qualified Person and Minor Deviations

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GROUPEMENT DES PHARMACIENS DE L'INDUSTRIE EN EUROPE

Overview

- EMEA Reflection Paper
- EIPG Working Group
- Comments of Interested Parties
- Conclusions



- It was published on March 2006
- It deals with *minor deviations* from the details described in the MA
- It is recognized that "from time to time minor deviations from the details set out in the MA application do occur"



- The issue is whether a QP may certify and release such batches
- No harmonised approach exists in the EU
- The proposal deals with the *one-off type of deviations*
- *Recurrent deviations* are outside the scope of the EMEA proposal



EMEA Reflection Paper

A simple and pragmatic approach is proposed, based on:

- 1. responsibility of QP to make decisions
- 2. principles of quality risk management
- 3. documentation made available on request



EMEA Reflection Paper

Application criteria:

- deviation is **minor**, **one-off**, **unplanned**
- deviation not affecting safety or efficacy
- API and finished products specs <u>not</u> involved
- to assess the need of an **on-going stability** test
- **QRM** to be integrated into the QA system
- all deviations to be reviewed as part of the AQR



- To minimise the occurrence of deviations, it is requested to remove *unnecessary details* from MA application
- Any deviation which may affect the *safety* or *efficacy* or compromises the *overall quality* must result in a QP decision <u>not</u> to release the batch



- A feedback was requested to all *interested parties*
- Amendment to Annex 16 was pointed out
- In February 2007 a new request of reply, <u>on a</u> <u>structured form</u>, was issued
- A meeting with *industry representatives and associations* was planned by September 2007



EIPG Working Group

- QP responsibilities and duties is part of EIPG strategic plan
- A Working Group was set up in Prague (2007 G.A.) to prepare a reply to EMEA
- All delegations were invited to give their comments and contributions
- An official EIPG document was submitted to EMEA on September 2007



EIPG Working Group

Innovative Issues

- promotion of *quality risk management* principles
- increase of *QP discretion* power and extension of responsibilities
- benefit in time response and in flexibility from *Regulatory Bodies*



EIPG Working Group

Critical Issues

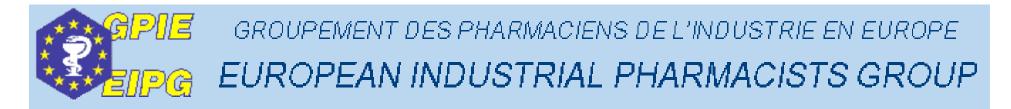
- a *cultural change* is required for the implementation of *QRM* principles
- reducing level of details in MA seems difficult to be applied to *existing dossiers*
- more flexible approach is required for dealing with *recurrent deviations*



EIPG Working Group

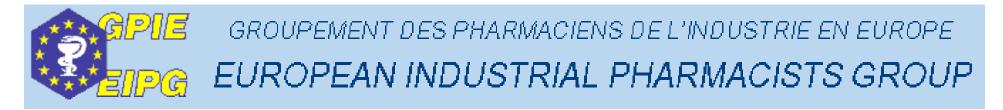
Key Points

- incorporation into *EU GMPs* (*Annex 16* and other sections of *GMPs*)
- *QP responsibilities* and *duties*
- *QP* reliance on the *quality system*
- extension of the principles to IMPs

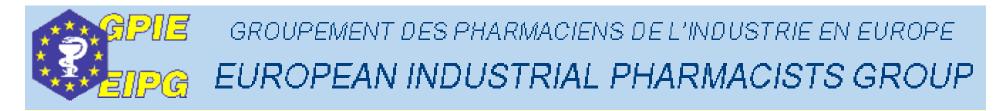


Meeting held in London on 26 Sept 2007 with:

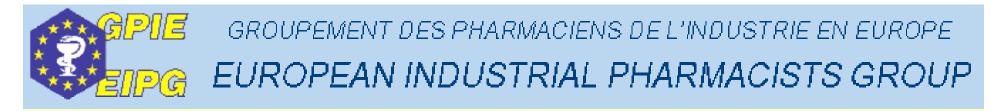
APIC/CEFIC EFPIA EGA **EIPG EQPA EVM IFAH-EU ISPE** PDA **PPTA AESGP**



- Most of *Interested Parties* presented detailed comments and suggestions
- EFPIA took the lead of the discussion
- A common position was agreed
- A presentation was made to EMEA



- Reflection Paper generally welcomed
- Most companies not aware of the Reflection Paper
- Proposal of EMEA not accepted by Authorities in some Member States
- Strong support on reducing level of details in MA dossiers



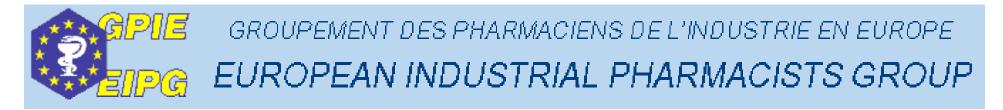
QP discretion should be broadened to include:

- \checkmark recurrent deviations
- ✓ minor changes, pending approval of a filed variation
- ✓ OOS deviations for non critical attributes
- ✓ deviations from IMP dossier

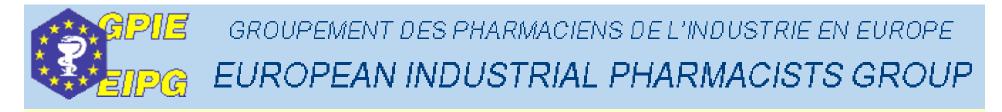
not impacting safety or efficacy



- **To extend the scope** to any minor deviation (starting and packaging materials specs, IPCs), provided that safety and efficacy are met
- To clarify that the QP involved in release of **intermediate stage products** may adopt the same principles
- To clarify that it is not always necessary to perform a **formal risk assessment**, but an informal analysis is acceptable



- The **Reflection Paper is too limited**, as it does not allow for the full qualification and accountability of the QP in batch release decision
- Interested Parties ready to actively contribute to revision of Annex 16 and GMPs to harmonise the QP role



- All comments presented to EMEA
 Principles of the Reflection Paper accepted by all Member States
 Harmonisation on QP role expected
 Agreement on the Annex 16 revision
- Further discussion required before implementation



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Conclusions

- 1. EIPG was officially recognised among the European professional bodies
- 2. Broadening of QP discretion power is the key issue for the next future
- 3. QP qualification and professional development is part of EIPG strategic plan