GPIE EIPG

GROUPEMENT DES PHARMACIENS DE L'INDUSTRIE EN EUROPE

EUROPEAN INDUSTRIAL PHARMACISTS GROUP

Qualified Person and Minor Deviations

P. Iamartino – EIPG Italian Delegate

Malta, 18th April 2008

Overview

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

EMEA Reflection Paper

- 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*"

EMEA Reflection Paper

- 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 not 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**

EMEA Reflection Paper

- 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 not to release the batch

EMEA Reflection Paper

- A feedback was requested to all *interested parties*
- Amendment to **Annex 16** was pointed out
- In February 2007 a new request of reply, on a structured form, 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*

Comments of Interested Parties

Meeting held in London on 26 Sept 2007 with:

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

Comments of Interested Parties

- 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

Comments of Interested Parties

- 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

Comments of Interested Parties

QP discretion should be broadened

to include:

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

<u>not impacting safety or efficacy</u>

Comments of Interested Parties

- **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

Comments of Interested Parties

- 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

Comments of Interested Parties

- 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

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