



Questions for QP – MHRA Discussion Forum 10th March 2004

Attendee number	Subject	Questions
12	Risk & PAT	What's MHRA's view on term 'Risk based GMP's' as referred to by FDA.
12	General GMP issues	What is MHRA's view on 'Quality System' audits'.
13	General GMP issues	Temperature control of dry products in shipment - sources indicate an expectation that normal dry products should be protected from the environment during shipment; GDP Guidelines section 20 MAIL may/June 2002. However, there seems little practical guidance on how it should be achieved. How do member companies ensure that these requirements are met? How extensive is the use of temperature monitoring devices for shipments of these materials? How involved are QPs in the assessment of the data generated?
4	QP	QP v RP for control of Cold Chain products: does the QP have a continuing responsibility here after batch release and how would this be exercised and/or shared with the RP in a distributor for a query about the integrity of the Cold Chain?
19	QP	A (virtual) Client Company has requested that we add one of their QPs to their company ML in order to release their own Clinical Trials products. Opinions please?
33	QP	What is the view on locum QPs. How should it be managed by manufacturers and QPs?
10	QP	What is being done by RSPGB, Industry or NHS to encourage more Pharmacists to become QPs?
25	IMPs	How is the MHRA going to prioritise inspections of IMP manufacturers / assembly sites and will it be performing overseas inspections?
36	IMPs	The impact of the Clinical Trials Directive. Update on status with the MHRA versus 1st May 04 implementation date bearing in mind that they have already implemented things.
11	IMPs	Will QPs for IMPs under the grandfather clause (on May 1st) be able to certify batches made in EU (not UK) and imported
28	IMPs	Within the new European regulations for IMPs can the QP requirements be clarified i.e. Register? Transitional? Who will be allowed to do what?
27	IMPs	What criteria are people using across the industry to decide who to name as QP on their MA(IMP)
27	IMP	Can MHRA confirm that an IMP licence will be required for sites that receive clinical supplies after the trial has terminated for reconciliation and destruction.
27	IMP	The IMP Licence Application Section 2 mentions Analytical Testing, can MHRA confirm that this relates only to contract testing sites and not QC testing by the site of manufacture
27	IMP	The IMP Licence Application Section 6 asks us to list all 3rd country sites of manufacture. Is this required as the MHRA stated that this information is required in the CTA not the IMP Licence.



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- 26 General GMP issues The Orange Guide clearly defines what constitutes a batch. In this age of automated packing lines have the members any experience of compromising that definition to avoid changeovers to print & if they do, how do they provide Certificates of Analysis?
- 29 General GMP issues How are PQG members dealing with the issues relating to returned goods from the market place following the article in MAIL 137 May/June 2003? Exported products are of particular interest.
- 15 General GMP issues Re.batch reconciliation for licensed product (oral healthcare). QP release is against quantity of product actually transferred from site. Due to intermittent automated product count events, quantity for release may not reflect yield quantity declared on batch document. A very tight acceptance criteria of 99.5 – 100.5% is being considered for introduction to address this situation. Comments required.
- 17 IMPs Will batch testing be required for IMPs imported from 3rd countries as with licensed pharmaceuticals. If yes, what are the implications?
- 18 IMPs If an IMP comparative product is procured from an ex –EU Third Country (not from the same organisation) how do we obtain a reference material for full analysis and any specific information that may be proprietary?
- 37 IMPs Clinical Trials Directive (not really a question refer it to questioner for more?)
- 23 General GMP issues The use of partially pre-printed booklet labels is becoming more widespread in the clinical trials arena. What level of detail should be included in the specifications for these booklets?
- 13 QP We all have systems in place to approve and monitor our suppliers of materials for our processes. What systems are in place to approve the use of other “service providers” to the industry? For example laundries, providers of calibration services, suppliers of laboratory reagents and media etc.
- 39 QP What are the responsibilities of the QP if they are asked to release products to markets outside the EEC that may not be in packaging for the destined market.
- 39 QP Where does the responsibility lie if you are dealing with a contractor that is not helpful, doesn't allow you full access, won't send you any batch documentation nor notify you of any changes or all deviations. But is the sole manufacturer of the products for your company that you then certify for release. If anything happens where does the QP certifying it for release stand.
- QP How are QPs complying with the latest requirements for cpd in the GMP Guide? Relates to Clinical trials, but not medicinal products.
- 30 QP Can QPs effectively perform their function when they are in a position where they cannot directly influence the quality assurance process?
- QP A QP and RP are now required to sign that they are in agreement with being nominated on a Licence. However, in the case of QP requesting their removal from a licence directly to the MHRA, they have said that they would act immediately on this request. Potentially the company could be left without a QP. What further action would the MHRA take?
- 10 Headcount Has there been any formal studies or benchmarking conducted by PQG, Industry or the professional bodies on the QA or QP headcount requirements compared to Production headcount for the various product types (tablets, LCOs etc c/t steriles)?
- General GMP issues How do companies control their artwork for printing. Do you use electronic files, pdfs etc and if so, do you also use a signed printed original copy for verification?