



Life Sciences Regulatory Update

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This Life Sciences Regulatory Update has been compiled from a survey of selected web-sites. The reported news is centred on the validation and use of computerised systems under GMP conditions. Comments and feedback are welcome to: per.olsson@gb.abb.com

1. FDA

<http://www.fda.gov>

In November the FDA issued **draft new guidance on the general principles and practices for process validation**. The original guidance dates back to 1987 and previous (unsuccessful) attempts have been made to update this guidance. Although automated computerised systems are not specifically covered by the guidance, this document is still of great interest as it defines the overall validation expectations and current regulatory thinking.

The definition of process validation has been updated to read: *Process validation is defined as the collection and evaluation of data, from the process design stage throughout production, which establishes scientific evidence that a process is capable of consistently delivering quality products.* Note that the word "documented" has been replaced by "data" and the word "scientific" has been added. There is no lessening in the documentation requirements, however!

A strong connection is made between the product and process life cycles, and the need for a *scientific* understanding of these life cycles. There is still a requirement that a *high degree of assurance* is gained that a process will produce a drug product meeting its identity, strength, quality, purity and efficacy (potency) attributes. The guidance stresses the importance of good project management and archiving. Comments on the draft guidance can be submitted to the FDA before the end of January 2009.

In September the FDA issued an update to the GMP regulation **Part 211**. The main change of interest is that where the regulation requires a second person to verify the operation by a first person, an automated system can replace one of the two individuals. This has been the long-standing understanding of the requirements, but now it has been clarified in the regulations. Note that where an automated system is used in this circumstance, the system must be compliant (read: validated). This update of Part 211 can be seen in the light of previous plans to rewrite the regulation, but this has now been rejected in favour of a limited update.

2. MHRA

<http://www.mhra.gov.uk>

In October the MHRA issued a **Good Pharmacovigilance Practice Guide**. This is a very topical subject and the guide can be applied across the EU. Unfortunately it is not available as a PDF file, but this 256 pages long book can be purchased from the Pharmaceutical Press (same publisher as for the 'Orange Guide').

It is interesting to note that the MHRA in September also updated its guidance relating to **Medical Device Vigilance**, also known as *Adverse Incident Reporting*.

In July the MHRA issued a 24 page brochure on the **Medicines and Medical Devices Regulations** and how they are enforced for the good of public health. Anyone new to the industry would benefit from reading this excellent short guide.

The MHRA has reminded us that in October this year the **Medicines Act** reached 40 years. At the same time MHRA announced that the act will be reviewed and consolidated as required.

3. EMEA

<http://www.emea.europa.eu>

The comment period for the new draft **GMP Annex 11** guidance on computerised systems is now over. So far there is no news on the outcome of the consultation, but suffice to say that there has been great interest amongst both industry and the regulators.

The same comment applies to **GMP Chapter 4** guidance on documentation. Both Annex 11 and Chapter 4 were extensively covered in the previous Regulatory Update, so will not be repeated here.

In August 2008 the GCP Inspectors Working Group issued a work plan. Amongst many things, the group will attempt to issue updated **guidance on the conduct of GCP inspections**. This covers five subject areas, and computerised systems is one of them, so it may be worthwhile looking out for this guidance when it is issued.

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4. ICH

<http://www.ich.org>

In June 2008 **ICH Q10** on Pharmaceutical Quality System reached 'step 4'. The guidance is now ready for adoption by the regulatory bodies of the US, EU and Japan. This is a very interesting document that is likely to have far reaching implications. It is stated that Q10 is based on ISO 9001 quality concepts and current GMP regulations, but Q10 goes further by defining a set of principles to adhere to. Interestingly, the guidance does not state that alternative approaches may be used, something we have grown so used to see in regulatory guidance.

The scope of the quality system is extended from the manufacturing phase to include pharmaceutical development, technology transfer and product discontinuation. As such it is aligned to the *Quality by Design* concept. The guidance deals with management responsibilities, process performance improvements, product quality improvements, and continual improvement of the quality system itself (this is consistent with ISO 9001). Q10 is also consistent with previously published ICH quality guides, and in particular Q7 on GMP for active ingredients, Q8 on pharmaceutical development, and Q9 on quality risk management. A key tenet running throughout the guidance is a risk-based approach based on scientific understanding of the product and the manufacturing process.

Not only has ICH issued the final version of Q10, but there is also a concept paper on the next quality guideline, namely **Q11** on the development and manufacture of drug substances. This could be an important step in finally harmonising drug GMPs across the globe, and it will be interesting to see how it fits in with the corresponding PIC/S guidance. The first draft (step 2) is due to be published by the end of 2009.

5. ISPE

<http://www.ispe.org>

Since the last newsletter the draft **GAMP Good Practice Guide for Maintaining Control in**

Operation has been out for public review, and the review period has now passed. Previously this draft guide was named *Maintaining the Validated State* and we look forward to its publication in 2009.

There is no news to report on other GAMP guides, ISPE Good Practice Guides and Baseline Guides. We are still waiting for the guides on Validation of Process Control Systems, Good Engineering Practice, and Installation and Verification.

6. PIC/S

<http://www.picscheme.org>

There is nothing of substance to report this time.

7. ABB Life Sciences

<http://www.abb.com/lifesciences>

ABB has been fortunate in securing the services of **Tony Trill**, who retired from the MHRA earlier this year after a distinguished career. Tony played a key role in the development of the GAMP guide, and became the focal point within the MHRA for all matters concerning computerised systems. ABB can offer the services of Tony in all aspects of GMP and computerised systems regulations, e.g. pre-inspection audits, inspection support, post-inspection consultancy, etc. In addition, Tony is qualified to act as a Qualified Person (QP) should the need arise. Further details on the services that Tony can offer in conjunction with ABB are available from ABB (Per Olsson).

ABB deliver a range of training courses for pharmaceutical manufacturers and suppliers alike. We have now converted a number of these course modules to a suitable **web-based training** format. This enables a low-cost alternative to classroom type training. The training material is enhanced through the use of confirmative questions and 'model' answers, a set of multiple choice questions to determine the effectiveness of the training, and certification by ABB on the successful completion of a set of course modules. For more information, please contact ABB (Per Olsson).

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ABB Engineering Services

Postal Address:
3100 Daresbury Park,
Warrington, WA4 4BT, U.K.

Telephone:
+44 (0)1925 741111

Fax:
+ 44 (0)1925 741212

Web Address:
www.abb.com/lifesciences