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

The FDA adopted **ICH Q10** in April 2009. Q10 was described in some detail in the December news-letter.

The **Regulatory Procedures Manual** was up-dated in March 2009. This document describes the working of the FDA. It also contains an exhaustive glossary (31 pages!).

2. MHRA

http://www.mhra.gov.uk

The MHRA has issued its **Business Plan for 2009/10**. This is interesting reading as it gives you an insight to where MHRA sees the primary target for its scarce resources. Examples of these include a focus on adverse event reporting and pharmacovigilance, tackling counterfeit drugs, medicines for children and inspections of blood establishments. None of these subjects are new and are well aligned with some of the priorities of the FDA. MHRA states clearly that a risk-based approach will continue to be taken for inspections. As a side issue, the agency will improve its own computer systems to ensure that security of critical data it holds is adequate.

MHRA's brief but excellent Bulletin 17 on **Medical Devices and Medicinal Products** has been up-dated, but the amendments appear to be limited.

Similarly, the Guidance Notes 1 on **Clinical Investigations for Medical Devices** has been up-dated.

3. EMEA

http://www.emea.europa.eu

A concept paper for the adoption of **ICH Q10** has been issued. Apart from adding Q10 as an appendix to EU GMP, chapters 1, 2 and 7 would also be amended to suit. The deadline for comments is 30 June 2009.

It is proposed to update the **GDP Guidelines**, with a draft being released later in 2009.

The Annex to **ICH Q8** has been adopted (see below).

A new draft of an expanded **Annex 14** of the GMP Guide has been issued, with comments received until 31 July 2009.

The new text for **Chapter 4** and **Annex 11** are expected in quarter 2 of 2009.

4. ICH

http://www.ich.org

In November 2008 the annex to **ICH Q8 on Pharmaceutical Development** was finalised (step 4). This annex deals with important and topical concepts such as *Critical Quality Attributes, CQA*, *Design Space* and *Control Strategy* under the umbrella of *Quality by Design* or *QbD*.

The **ICH Publication Library** has recently been established and has some useful help documents, such as a comprehensive briefing pack on *ICH Q9* and an overview presentation of *ICH Q10*. For example, there are succinct PowerPoint presentations on *Fault Tree Analysis*, *HAZOP*, *FMEA* and other risk assessment methodologies. There is also some interesting material arising from a 3-day conference on Q8, Q9 and Q10 held in China in December 2008.

It is worth noting that the ICH has produced a specification on **Electronic Common Technical Document, eCTD**. The specification is based on XML and should be useable in the EU, US, Canada and Japan. Although this is not new, the web-pages are being kept up-to-date, so for anyone involved in regulatory submissions, this is probably a space well worth visiting.

5. ISPE

http://www.ispe.org

In December 2008 the Good Practice Guide on **Good Engineering Practice, GEP,** was issued. This guide covers three main areas, namely project engineering, operations & maintenance, and common practices, such as change control and documentation standards. The strength of this guide is probably in its attachments, which cover a large number of items such as site development plan, project change control, design reviews, GMP assessments, system boundaries, completion

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checklist, etc. It should be noted, however, that the guide is largely generic, apart from the project management related tasks, and will not tell you what good engineering practice entails for each discipline, such as electrical engineering, system engineering, etc. This is the main weakness with this guide, but it was probably always unrealistic to hope that it would also "transpose" GEP to all the key disciplines.

It is gratifying to note that the GEP guide promotes separate **User Requirement Specifications, URS**, for the project and system elements. This has been advocated by ABB for some time, and is encompassed in our QMS *Streamlined Validation*.

Good Engineering Practice underpins **GAMP5** and is an essential overarching element of the **ASTM E2500** standard guide for the specification, design and verification of manufacturing systems and equipment. But this doesn't get away from the requirement that GEP needs to be applied in the execution of each discipline, something that is not always very well codified, system engineering being a good example.

It is disappointing to note that the long awaited up-date of the GAMP Good Practice Guide on **Validation of Process Control Systems, VPCS**, has still not been released. It is understood, however, that the draft edition contains an interesting section on *PAT*, so we look forward to reviewing this guide in due course.

Finally, ISPE has announced four new **Baseline Guides** that are scheduled to be released in 2009. These cover *Maintenance*, *Quality Laboratory Facilities*, *Risk-based Manufacture of API*, and *ASTM E2500*.

6. PIC/S

http://www.picscheme.org

PIC/S is continuing to increase its influence and cooperation with other bodies. The French Agency for Veterinary Medicinal Products, ANMV, and Israel's Institute for Standardisation and Control of Pharmaceuticals (ISCP) have recently joined PIC/S. In November 2008 a workshop was hosted jointly with PDA and ISPE. PIC/S has also signed a cooperation agreement with UNICEF. The latter in particular demonstrates that the influence of PIC/S potentially extends beyond its member states. It is also worth noting that the new draft EU Annex 11 makes heavy references to the PIC/S guide on computerised systems.

The **Guide to GMP for Medicinal Products, PE 009** has been revised in January 2009 and is now at revision 8. Chapter 1 and Annex 1 have been updated and Annex 20 on quality risk management has been added with the proviso that it is voluntary. This update brings the PIC/S guide into line with the EU GMP guide.

PIC/S has also issued a couple of new aid memoirs. The **Inspection Guide on Packaging, PI-028**, asks only one question that is directly related to computerised system: "How do you ensure the security of the data entry in the electronic batch packaging record, BPR?" Of course, this question is relevant not just to packaging records, but all critical entries!

The **Inspection Guide on Active Pharmaceutical Ingredients, PI-030**, which is based on ICH Q7, asks "have computerised systems been validated?" and "have the backup systems been verified?" Again, these are fundamental questions for any regulated computerised system, so should not come as any surprise.

7. ABB Life Sciences

http://www.abb.com/lifesciences

ABB is planning the imminent launch of its **System Migration Compliance** product or **SMC** for short. This is aimed at filling an identified gap between the typical System Integrator and the User. SMC encompasses business assurance, project management assurance as well as technical regulatory assurance, and this is delivered through a toolbox that includes tailored action plans taking a risk-based approach to compliance. More information to follow!

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