Courses "GxP in biomedical research"
21-22 July 2015, Bonn, Germany

Preliminary program of courses

July 21, 2015

Prof. Dr. Harald Schweim

A1 Regulatory Affairs: NEW EU-Regulation, focussing on biologicals, biomedicals, biosimilars etc.

Dir. u. Prof. Dr. Usfeya Muazzam,

A2 GMP What? Why? How? Directives. ICH Q7, Q9, Q10
A3 GMP Quality without compromise - how? Quality improvement.
A4 GMP Compliance. Inspections. Deficiencies.

Prof. Dr. Jürgen Pomp

01 GLP Basics (laws, regulations, focus)
02 GLP Test facility (Laboratory, units, roles and responsibilities)
03 GLP SOP system (Establishing and maintenance of the SOPs)
04 GLP Training and mentor system

July 22, 2015

Prof. Dr. Jürgen Pomp

05 Planning and conduct of GLP studies (from study protocol to archive)
06 Testing equipment and computers under GLP, incl. practical examples
07 Documentation and archiving (good documentation practice), incl. practical examples
08 Audits and inspections (internal, external, authority inspection)

July 24, 2015

Visit to Finzelberg AG, GMP certified production of herbal extracts.