



Univ. - Prof. Dr. rer. nat. habil. Harald G. Schweim
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Fachapotheker für Arzneimittelinformation und für öffentliches Gesundheitswesen
Lebensmittelchemiker und Medizininformatiker (GMDS/GI)
Ehem. Direktor des Deutschen Instituts für Medizinische Information und Dokumentation
Präsident und Professor des Bundesinstituts für Arzneimittel und Medizinprodukte a.D.
Ehm. Geschäftsführender Direktor des Pharmazeutischen Instituts



We hereby certify that

Dr. Elena Shekunova

Has successfully attended a course for "GxP in Biomedicine" by Univ. - Prof. Dr. rer. nat. habil. Harald G. Schweim (RFWU-Bonn) at the occasion of the PHYTOPHARM 2015, jointly co-organised with Prof. Dr. Jürgen Pomp (Hochschule Bonn Rhein-Sieg) and Direktor und Professor Dr. Usfeya Muazzam (former "Federal Institute for Drugs and Medical Devices" Bonn).

Content of the course:

- A01 GRP Introduction in Regulatory Topics in Biomedical Research
- B02 GMP What? Why? How? Directives. ICH Q7, Q9, Q10
- B03 GMP Quality without compromise - how? Quality improvement
- B04 GMP Compliance. Inspections. Deficiencies
- C05 GLP Basics (laws, regulations, focus)
- C06 GLP Test facility (Laboratory, units, roles and responsibilities)
- C07 GLP SOP system (Establishing and maintenance of the SOPs)
- C08 GLP Training and mentor system
- C09 GLP Planning and conduct of GLP studies (from study protocol to archive)
- C10 GLP Testing equipment and computers under GLP, incl. practical examples
- C11 GLP Documentation and archiving (good documentation practice), incl. practical examples
- C12 GLP Audits and inspections (internal, external, authority inspection)

12 hours of 60 min. plus 4 hours regulatory program of the PHYTOPHARM 2015 (21.- 22.07.)

Jürgen Pomp

Harald G. Schweim

Usfeya Muazzam