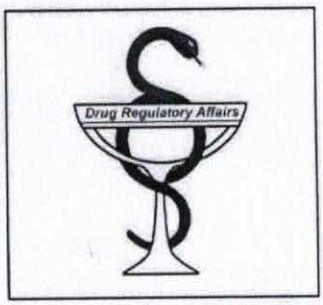
universitätbonn

Hochschule
Bonn-Rhein-Sieg
University of Applied Sciences

BfArM
Federal Institute for Drugs and Medical Devices

Univ. - Prof. Dr. rer. nat. habil. **Harald G. Schweim**
Lehrstuhl für „Drug Regulatory Affairs" der RFW-Universität Bonn
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

Mrs. Khodko S.V

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
Prof. for Quality Assurance and Forensic Analysis	Univ.-Prof. for Drug Regulatory Affairs	Dep. Head of Dep. Pharm. Quality at BfArM (ret.)