

**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. Dr. Marina Makarova**

Has successfully attended a course for "GxP in Biomedicine" by Univ. - Prof. Dr. rer. nat. hab. 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 Prof. 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

Prof. for Quality Assurance and Forensic Analysis

Harald G. Schweim

Univ.-Prof. for Drug Regulatory Affairs

Usfeya Muazzam

Dep. Head of Dep. Pharm. Quality at BfArM (ret.)