

# Vereinstreffen der AQPA

Inspektionen durch die Russischen Gesundheitsbehörden

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*Auszüge aus  
EFPIA\* – shared experiences of Inspections from  
Russia National Competent Authorities (RNCA),  
David Ross, Stephan Rönninger Jan 2017*

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# Russia National Competent Authorities Inspections

- Importation of products into Russia requires
  - **GMP certificate** issued by RNCA after a successful GMP inspection
  - pharmaceutical legislation in Russia, **no recognition by other authorities**, 3 years implementation period
- Learnings - Preparation
  - Focus on **normative document** = specific reg. document (DP Specifications, anal. Methods, quality information) → differences, gaps = potential critical non-conformances → justification & variation to be submitted before the Inspection
  - assistance of **Russian speaking affiliate company**
    - Language & interpretation of legislation framework
    - data driven justification for the use of more advanced, non-pharmacopoeia methods

# Russia National Competent Authorities Inspections

- Learnings - Inspection Management
  - Discussions between Russian speaking affiliate's representative and the inspectors are key for early identification of potential issues
  - non-conformances
    - issues discussed during inspection can be raised during final close out
    - initial classification in inspection report → concern regarding GMP certificate
  - response → provide information to clarify (+ same as presented during inspection) → lower classification → issuance of GMP-certificate
- Topics
  - Differences from Eudralex GMP
    - Validation of air flows
  - Pressure diff. in compliance with Russian GMP (10-15 Pa between clean zones)
  - Humidity monitoring for products to be “stored in a dry place”
  - Dedicated facilities for ATC L1 products \*(Chemotherapeutics)

\* ATC code L: Antineoplastic and immunomodulating agents is a section of the Anatomical Therapeutic Chemical Classification System, a system of alphanumeric codes developed by the WHO for the classification of drugs and other medical products.