PDA
Parenteral Drug Association
Connecting People, Science and Regulation®

PDA Europe gGmbH

General Manager:
Georg Roessling, PhD
Sr. Vice President
Adalbertstraße 9
16548 Glienicke
Germany
Tel: +49 (33056) 2377-10
Fax: +49 (33056) 2377-77
www.pda.org

31 August 2011

Secretariat, Biologics Working Party (BWP)
European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom
BWPSecretariat@ema.europa.eu

Reference:
Concept paper on the need for a guideline on process validation of medicinal products containing biotechnology derived proteins as active substance
(EMA/CHMP/BWP/25360/2011, 19 May 2011)

To: Secretariat, EMA/Biologics Working Party (BWP)

PDA is pleased to have the opportunity to comment on the referenced concept paper proposing a guideline on process validation for protein biotech medicinal products. We have three general comments regarding such a guideline.

1. Value to stakeholders: We support preparation of an appropriate process validation guideline to the extent that it facilitates the quality, manufacture and registration of such medicinal products.

2. Modern quality principles: The guideline should incorporate, and be consistent with, the validation principles and terminology found in ICH Q5, Q6 and Q7, and also the quality concepts embraced by Q8, Q9, Q10 and (when finalized) Q11.

3. Prior knowledge: To the extent useful, the guideline should consider and be consistent with existing industry guidance, 'points to consider,' and consensus-based technical information relating to process validation for medicinal products.

Consistent with point No. 3, PDA is including in our comment matrix a listing of our published Technical Reports which should be helpful for the BWP drafting group. Copies of these Technical Reports will be forwarded to the BWP Secretariat under separate cover.

Thank you again for the opportunity to support the consultation process. Please contact me, or James Lyda of the PDA staff (lyda@pda.org), if you have questions.

With very best regards,

Georg Roessling, Ph.D.
Senior Vice President, PDA Europe
Roessling@pda.org

cc: S. Rönninger, S. Schniepp, J. Lyda, R. Levy, R. Dana,

31 AUGUST 2011

Concept paper on the need for a guideline on process validation of medicinal products containing biotechnology derived proteins as active substance (EMA/CHMP/BWP/25360/2011, 19 May 2011)

Deadline for comments: 31 August 2011

Comments from: PARENTERAL DRUG ASSOCIATION (PDA)

Name of organisation representative : James C. Lyda, lyda@pda.org

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

1. General comments

PDA No.	Stakeholder No.	General comment (if any)	Outcome (if applicable)
1		Value to stakeholders: We support preparation of an appropriate process validation guideline to the extent that it facilitates the quality, manufacture and registration of such medicinal products.	
2		Modern quality principles: The guideline should incorporate, and be consistent with, the validation principles and terminology found in ICH Q5, Q6 and Q7, and also the quality concepts embraced by Q8, Q9, Q10 and (when finalized) Q11.	
3		Prior knowledge: To the extent useful, the guideline should consider and be consistent with existing industry guidance, 'points to consider,' and consensus-based technical information relating to process validation for medicinal products. We offer the following PDA Technical Reports in support of the drafting process (to be emailed to BWP Secretariat under separate cover): - No. 14 - Validation of Column-Based Chromatography Processes for the Purification of Proteins, 2008 (rev) - No. 15 - Validation of Tangential Flow Filtration in Biopharmaceutical Applications, 2009 (rev) - No. 26 - Sterilizing Filtration of Liquids, 2008 (rev) - No. 28 - Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals, 2006 (rev) - No. 38 – Manufacturing Chromatography Systems, Post-Approval Changes (Chrompac): Chemistry, Manufacturing and Controls Documentation, 2006 - No. 42 - Process Validation of Protein Manufacturing, 2005 - No. 44 - Quality Risk Management for Aseptic Processes, 2008 - No. 49 - Points to Consider for Biotechnology Cleaning Validation, 2010 (rev) - No. 50 - Alternative Methods for Mycoplasma Testing (2010)	