Accepted Manuscript

An Inter-Company Perspective on Biopharmaceutical Drug Product Robustness Studies

Sorina Morar-Mitrica, Monica L. Adams, George Crotts, Christine Wurth, Peter M. Ihnat, Tanvir Tabish, Valentyn Antochshuk, Willow DiLuzio, Daniel Dix, Jason Fernandez, Kapil Gupta, Michael S. Fleming, Bing He, James K. Kranz, Dingjiang Liu, Chakravarthy Narasimhan, Eric Routhier, Kathy Taylor, Nobel Truong, Elaine Stokes

PII: S0022-3549(17)30715-3

DOI: 10.1016/j.xphs.2017.10.017

Reference: XPHS 965

To appear in: Journal of Pharmaceutical Sciences

Received Date: 6 April 2017

Revised Date: 5 October 2017 Accepted Date: 6 October 2017

Please cite this article as: Morar-Mitrica S, Adams ML, Crotts G, Wurth C, Ihnat PM, Tabish T, Antochshuk V, DiLuzio W, Dix D, Fernandez J, Gupta K, Fleming MS, He B, Kranz JK, Liu D, Narasimhan C, Routhier E, Taylor K, Truong N, Stokes E, An Inter-Company Perspective on Biopharmaceutical Drug Product Robustness Studies, *Journal of Pharmaceutical Sciences* (2017), doi: 10.1016/j.xphs.2017.10.017.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.



ACCEPTED MANUSCRIPT

An Inter-Company Perspective

on Biopharmaceutical Drug Product Robustness Studies

Sorina Morar-Mitrica^{1,*}, Monica L. Adams², George Crotts¹, Christine Wurth³, Peter M. Ihnat⁴, Tanvir Tabish⁵, Valentyn Antochshuk⁶, Willow DiLuzio⁷, Daniel Dix⁸, Jason Fernandez⁹, Kapil Gupta⁹, Michael S. Fleming¹⁰, Bing He¹¹, James K. Kranz¹¹, Dingjiang Liu⁸, Chakravarthy Narasimhan⁶, Eric Routhier¹², Kathy Taylor¹¹, Nobel Truong⁷, Elaine Stokes¹³

¹ Biopharmaceutical Product Sciences, GlaxoSmithKline R&D, 709 Swedeland Road, King of Prussia, PA 19406, USA

² Drug Product Science and Technology, Bristol-Myers Squibb, One Squibb Drive, New Brunswick, NJ 08903, USA

³ Pharmaceutical Development & Supplies, PTD Biologics Europe, F. Hoffmann-La Roche Ltd., Basel, Switzerland

⁴ Biologics Preformulation and Drug Product Development, Abbvie Bioresearch Center, Worcester, MA 01605, USA

⁵ Shire Pharmaceuticals, Industriestr 72, 1221 Vienna, Austria

⁶ Merck & Co., Inc., Biologics and Vaccines Development, 2000 Galloping Hill Road, Kenilworth, NJ 07033, USA

⁷ Formulation Development, Takeda Pharmaceuticals International Co., 40 Landsdowne Street, Cambridge, MA 02139, USA

 ⁸ Regeneron Pharmaceuticals Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, USA
⁹ Biogen, 14 Cambridge Center, Cambridge, MA 02142, USA

¹⁰ Analytical & Pharmaceutical Sciences, ImmunoGen, Inc., 830 Winter Street, Waltham, MA 02145. USA

¹¹ Shire, 300 Shire Way, Lexington, MA 02421, USA

¹² Pharmaceutical Development, Alexion Pharmaceuticals Inc., 100 College Street, New Haven, CT 06510 USA

¹³ BioPhorum Operations Group, Sharrow Vale Road, Sheffield, S11 8YZ, United Kingdom

^{*} Correspondence to: sorina.2.morar-mitrica@gsk.com

Download English Version:

https://daneshyari.com/en/article/8513445

Download Persian Version:

https://daneshyari.com/article/8513445

<u>Daneshyari.com</u>