From: Belsky, Kimberly [Kimberly.Belsky@bausch.com]
Sent: mercredi 28 décembre 2011 13:13
To: SANCO GMP; ADM-GMDP@ema.europa.eu
Subject: Regarding: Public consultation of the revised Commission guidelines on Good Distribution Practice of Medicinal Products for Human Use

Dear Sir or Madam:

On 15 July 2011, DG SANCO launched a public consultation on the revised guidelines for good distribution practices . The announcement noted that the content of the Guidelines on Good Distribution Practice published in 1994 is no longer adequate and the documented needed to be reviewed to take into account advancements of practices for an appropriate storage and distribution of medicinal products in the European Union. Moreover, it needed to consider the new requirements for wholesale distributors and brokers established by the new Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

Bausch + Lomb is one of the best-known and most respected healthcare companies in the world. Our core businesses include contact lenses and lens care products, ophthalmic surgical devices and instruments, and ophthalmic pharmaceuticals. Founded in 1853, our company is headquartered in Rochester, N.Y., and employs more than 10,000 people worldwide. Our products are available in more than 100 countries.

We appreciate the opportunity to provide comments on the proposed revised guideline. We support the Commission in its efforts to create updated guidance that reflects advancement in practices and new requirements for wholesale distributors and brokers as established by Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use In that respect, we offer the following comments:

Section	B+L Comment
Chapter 1 - Quality Management Sections 1.12 – 1.13: Quality Risk Management	(1) Quality Risk Management is a new concept introduced in this updated GDP guideline. As such, we recommend that additional detail be included to provide guidance on this concept. Specifically, we recommend that rather than a general reference to ICH, p. 7 of the Guideline expressly refer to ICH Q9 Quality Risk Management. (2) Section 1.12 states, "It can be applied proactively and retrospectively." Because of the broad applicability of this guideline, we believe it is important to emphasize that quality risk management is an ongoing evaluation rather than a finite or one time activity. We recommend that Section 1.12 be revised to clearly state the ongoing nature of quality risk management. Language may be incorporated from ICH Q9 as follows, "Risk management should be an ongoing part of the quality management process. A mechanism to review or monitor events should be implemented…." Additionally, we request that the concept of an ongoing assessment be added to the Annex Glossary of Terms for "Quality Risk Management". http://www.emea.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002873.pdf
Chapter 2 – Personnel Sections 2.1 – 2.5: Responsible Person	As per Section 2, satisfactory quality and correct distribution "relies upon people." The requirements outlined in the draft guideline address a variety of activities of the "responsible person" and we believe may be further enhanced by including communications to the customer. Specifically, we recommend adding a statement to Section 2.5 to emphasize the importance of communicating modifications as they relate to change control (e.g., Section 3 Premises and Equipment / Qualification and Validation) to the customer. Preferably this communication would be prior to the change being implemented. Communication to the customer is critical to managing risk assessment and deviations.
Chapter 3 – Premises and Equipment Section 3.26-3.29: Qualification and Validation	The Qualification and Validation section lacks specificity for distribution centers and may be enhanced by including additional details regarding the scope of validation activities. For example, Section 3.27 states, "Prior to the implementation and after any significant changes or upgrades, systems should be validated to ensure correct installation and operation." Inclusion of change control, risk assessment, and communication with the customer in this section would help to ensure a comprehensive quality process.
Chapter 8 – Self Inspections Section 8.1-8.2 Self-Inspections	Section 8.1 states, "A self-inspection programme should be implemented…within a defined time frame…." To emphasize that self-inspections are an ongoing activity, we recommend that "a defined time frame" be revised to include "according to an audit plan." Section 8.2 states, "Self-inspections should be conducted …by designated competent person(s) from the company." To ensure a consistent interpretation and application of "competent", we recommend that this Guideline reference the appropriate ISO standard(s) (e.g., ISO 19011 "Guidelines for quality and/or environmental management systems auditing".
Chapter 9 – Transportation Sections 9.17-9.23	The document provides guidance on transportation of product requiring special conditions and temperature control during transport. To incorporate current advancements and initiatives, we recommend that this section specifically include the concept of quality risk management to manage specific storage conditions (e.g., temperature and humidity).
Annex Glossary of Terms	To ensure a consistent application of "Supplier" (as used in Chapter 5: Operations) and "Subcontractor" (as used in Chapter 7: Contract Operations and Chapter 8: Self-Inspections), we recommend that these terms be added to the Annex Glossary of Terms. For example, it is unclear if Chapter 8 applies to the contractor and/or supplier audits. We believe addition of these terms to the Glossary will help clarify these ambiguities.

Kind regards,

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