Q&A | Interview

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“Our quality standards are simple: Do everything better.”

Interview by
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1. How did the regulatory environment for excipients change over the years?

In the past, regulatory agencies, drug manufacturers, and academia focused primarily on active pharmaceutical ingredients (APIs). Excipients were seen as inert and unimportant within formulations. Today, this concept has changed fundamentally. While APIs continue to be a primary focus, with increasing scientific knowledge and the growing need for overcoming increasing API challenges, excipients are under greater scrutiny with an emphasis on excipient safety and variability. Regulatory agencies try to cope with the exceptional evolution of excipients towards high functionality considering their novel importance in formulation.

2. What does that mean for the regulation of excipients?

Over the past several years, there has been an array of new or revised regulatory standards, implemented in the US and Europe. Just to name a few: since 2013, the so called FMD in Europe, which was recently supplemented by the Guideline on Risk Assessment (2015/C95/02) for excipients, was introduced and became legally binding by mid-2015. In the US, as a consequence of the FDASIA, NSF/IPEC/ANSI 363-2014 recently came into effect.

3. How did MEGGLE react to those changes?

MEGGLE initiated preparations years ago by tuning our quality systems to those regulations and ultimately obtain certification from the appropriate quality standards like EXCiPACT® for GMP and GDP. Furthermore, MEGGLE has seen to it that the supply chain, that is, our distribution network, has been fully integrated into this system. All MEGGLE's distribution partners have distribution agreements, making the IPEC-GDP guidelines mandatory and are bound by quality agreements. MEGGLE also encourages our distribution partners to enter into quality agreements with the customers and have provided templates for this purpose.

4. How important are other regulatory aspects, like QbD, PAT and Elemental Impurities for MEGGLE?

MEGGLE have continually monitored those developments closely since their introduction or proposal, and over the years and have adapted our quality systems, analytical procedures, and process technologies to fulfill those requirements once implemented. MEGGLE is ready to provide customers with "ObD" samples and has established elemental impurity profiles in accordance with (ICH-Q3D) in advance off USP <232> and <233> and EP (EMEA/CHMP/ICH/353369/2013) implementation.

5. Did the membership in industrial organizations help MEGGLE to facilitate those adjustments?

Yes, greatly. MEGGLE is an active member of IPEC, APV/APGI, EP, and industry-related organizations and are participating with several working groups in each. Therefore, MEGGLE is informed about upcoming developments and can participate in drafting industry and regulatory standards, enabling MEGGLE to respond well in advance to those changes and improvements within our own organization.

6. What other means does MEGGLE have to support customers in regulatory and quality aspects?

An important issue for most customers is risk mitigation and contingency plans. In practice, MEGGLE follows a double-sourcing policy, maintaining two production facilities with equivalent manufacturing processes and quality policies, and identical procedures and quality standards. Furthermore, MEGGLE has implemented contingency plans for our sites, which deals with all aspects of uninterrupted business operations and supply in case of emergencies. Additionally, MEGGLE has prepared Excipient Information Packages (EIPs), which contain all relevant information for the customers to facilitate required risk assessment.

7. How does MEGGLE address the area of continuous improvements?

In cooperation with R&D, MEGGLE monitors and is working jointly to improve processes, e.g. product crystallization to increase yields and reduce impurities, by installing state-of-the-art equipment and analytical procedures. Additionally, MEGGLE also monitors and analyzes non-specified and functional parameters to identify trends and areas for further improvement.

8. Is MEGGLE also actively involved in development processes of customers?

Aside from technical support, MEGGLE offers customers proactive complaint management. MEGGLE also maintains several application laboratories around the globe, as well as a research center, which supports customers in the development of various types of oral solid dosage formulations. MEGGLE is also providing expertise in related topics, such as coating, dry powder inhalation, and modified release formulation development. In addition to internal capabilities, MEGGLE maintains a network of international experts at universities and scientific institutes to offer customers solutions to challenges.

9. How do you see the significance of quality aspects and the role of quality management in the excipient industry nowadays?

The importance of excipients in the pharmaceutical industry has undergone some substantial changes in the last decade, which can be seen in a multitude of regulatory and legal frameworks dealing with excipients. Accordingly, the role of quality and management has changed and become the pivot point in the excipient industry. Today, customers and regulatory authorities expect the same quality standards and the same quality management as for active ingredients and finished dosage forms. MEGGLE, as excipient manufacturer, must comply with those requirements, and only those who are willing and able to do so, will ultimately survive. This may require consolidation in the excipient industry, but it will also mean substantial improvements for the patients and consumers of medicines.

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About MEGGLE:

MEGGLE AG, with its headquarters in the Bavarian city of Wasserburg (Germany), serves as a holding company for various business activities in the dairy industry and whey processing. MEGGLE has a proud history of more than 125 years in the dairy market.

The business group Excipients & Technology produces pharmaceutical excipients for direct compression, granulation, capsules, sachets, powder blends and dry powder inhalers. With its broad product portfolio, intelligent innovations and exceptional product quality, MEGGLE took a leading role in the global business of pharmaceutical excipients.

For more information please visit www.meggle-pharma.com

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