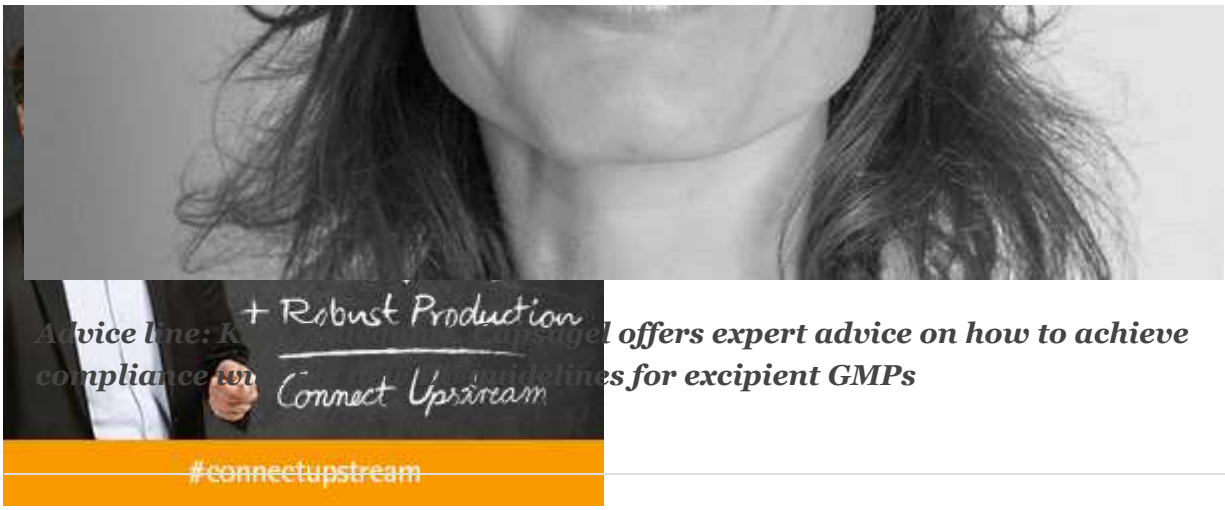
One step up: achieving compliance for excipient GMPs

by Kaat Bracquiné

Kaat Bracquiné, quality and regulatory affairs, Capsugel explains how to achieve compliance with the new EU guidelines for excipient GMPs



Advice line: K… offers expert advice on how to achieve compliance wi… guidelines for excipient GMPs

Last year, the European Union published new guidelines (2015/C 95/02) that require the pharmaceutical industry to demonstrate appropriate excipient Good Manufacturing Practices (GMPs) through a formalised risk assessment. As of the implementation deadline in March 2016, pharmaceutical companies should have conducted these formalised risk assessments and have them available to EU regulatory inspectors.

Excipient GMPs provide assurance that excipients are consistently produced and controlled to the quality standards appropriate to their intended use and as required by product specification. The EU guidelines require all manufacturing authorization holders to:

- Determine the risk profile of each excipient, taking into account the excipient source (animal, mineral, synthetic, etc.) and its use and function in the medical product;
- Determine the appropriate GMP, associated with the risk of the excipient;
- Perform a gap analysis of the activities and capabilities of each

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…g published mandatory GMP standards for …excipients. As a result for many pharmaceutical … since the industry uses a wide variety of …ed for numerous applications and …compliance with the guidelines can prove a real challenge.

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Given these obstacles, some pharmaceutical companies may not yet be prepared for the new EU guidelines. Now that the deadline has passed, companies that have not completed their formalised risk assessments face the potential of EU regulatory warnings and other actions. With that in mind, what steps can these companies take to more quickly achieve compliance with the EU guidelines?

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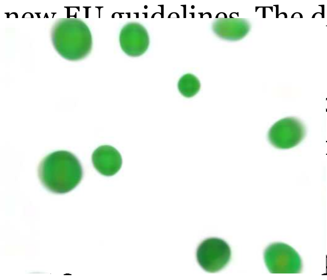
Cost, pharmaceutical companies can reference recommendations from their industry peers. For example, the International Pharmaceutical Excipients Council Europe (IPEC Europe), the industry association for producers, distributors and users of pharmaceutical excipients, recently published a comprehensive 'how-to' document to help pharmaceutical companies comply with the new EU guidelines. The document, released in March, includes practical and technical ... implement the steps necessary to achieve compliance. Additionally, ... contains several useful annexes, with a.o. legislative tools for risk ... f available GMP/quality standards facilitating gap analysis with the ...



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... panies can seek out specialised excipient manufacturers – some of which, like Capsugel, participated on IPEC Europe's risk-assessment task force to develop the ... ment – which have long invested in excipient GMPs and other quality initiatives to ... ed regulatory requirements. Among the key offerings to look for:

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1. **Independent GMP Certification:** Specialized excipient manufacturers with EXCiPACT-certified facilities can help pharmaceutical customers to significantly reduce their efforts needed to prove compliance with the new EU guidelines. EXCiPACT certification provides credible, independent validation that the excipient manufacturer maintains excipient GMPs and complies with current EU regulations. This certification may replace the on-site audit of excipient manufacturers by pharmaceutical companies, saving timing and resources. In 2014, Capsugel became the first hard capsule manufacturer to receive independent EXCiPACT certification for excipient GMPs at our facilities in Bornem, Belgium and Colmar, France. To date, Capsugel remains the only capsule manufacturer to receive this certification.

1. **Useful Regulatory Compliance Support Packages:** Specialised excipient manufacturers that offer compliance support packages for their products can help pharmaceutical companies with compliance efforts. These packages assist customers in completing their risk assessment by providing current technical information on the starting materials of their products to help facilitate required risk-scoring. They can replace the resource-intense process of collecting excipient product information linked to source and origin, which is required by the EU guidelines.

1. **Ongoing Regulatory Expertise:** Specialised excipient manufacturers that are involved and active in IPEC Europe, and thoroughly adhere to IPEC standards, offer pharmaceutical customers with useful experience and understanding of the changing excipient requirements in Europe. These manufacturers can advise companies on ways to achieve and maintain compliance in today's fast-changing regulatory environment, and are committed to transparent communication and change notification.

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