



ADVANTAGES OF EXCIPIENT GMP CERTIFICATION

by Jim Morris

Making a case for GMP certification of an excipient manufacturer should be a straightforward exercise since the benefits appear so clear cut and regulatory guidance in the EU underscores the value of certification. Specifically, Chapter 3 of the EMA Guidance on formalized risk assessments to determine the appropriate GMP for a pharmaceutical excipient states that "certification of quality systems and/or GMP by the excipient manufacturer and the standards against which these have been granted should be considered as such certification may fulfil the requirements". Furthermore, FDA participation in the development of a consensus standard, NSF/IPEC/ANSI 363 Good Manufacturing Practices (GMP) for Pharmaceutical Excipients, reinforces agency interest in ensuring pharmaceutical excipients are manufactured to an appropriate GMP standard. This article summarizes the benefits of an excipient GMP certification program (ECP) both from the point of view of the excipient manufacturer and the excipient customer.

BENEFITS TO THE EXCIPIENT MANUFACTURER

As an excipient certification body, one of the primary benefits is significantly improved quality systems and quality compliance at the excipient manufacturer. We have seen these improvements in the months leading up to GMP certification and continuing during the years immediately following GMP certification. Some excipient manufacturers were already at a high level of GMP compliance, and GMP certification provided confirmation of the maturity of their quality program. Other manufacturers needed to make significant improvements to their quality systems and, in some cases, their facilities in order to meet the requirements of the NSF/IPEC/ANSI 363 standard.

Yet, both groups of companies have realized the benefit of increased operator risk awareness, more effective internal audits, greater process understanding, increased cross-functional communication, and clear evidence of management's commitment to quality management principles. These benefits are often difficult to monetize however a single problem avoided through increased operator GMP awareness can result in significant cost avoidance.

BENEFITS TO THE EXCIPIENT CUSTOMER

Excipient customers will typically modify their oversight of excipient manufacturers that have been GMP certified. They may move the excipient manufacturer further down on their supplier risk profile and choose to audit less frequently, if at all. Excipient customers are aware that in order to be certified, the excipient manufacturer must have systems in place and provide evidence that non-conformances and changes that require customer notification are handled appropriately. This assurance is typically not obtained through a one-day supplier audit that pharma companies carry out; rather, it is obtained as a result of thorough, multiple day audits of an excipient manufacturer as part of a certification audit program.

The benefit of an ECP for the excipient customer should be close to zero surprises and very low regulatory risk. Furthermore, excipients received from GMP certified manufacturers are excellent candidates for a reduced QC testing program.

Pharmaceutical excipient customers, particularly biopharmaceutical customers, are increasingly requesting more technical information to justify their selection of excipients. Therefore, it would be of far more value for the excipient customer to focus on the technical aspects of the excipient it is purchasing and worry less about



GMP compliance once the excipient manufacturer is GMP certified. That is where the true value lies for both parties and ultimately for the end user or patient.

Consider the above benefits and select a certification scheme – such as NSF’s ECP – which will deliver long-term GMP improvement at your company, embed a culture of quality, and help your company establish a high level of confidence and trust with your excipient customers. If you are an excipient customer, select a GMP certified excipient manufacturer and reduce supply chain risk while freeing up resources to devote to other areas of the business.

ABOUT THE AUTHOR



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5 STEPS TO EXCIPIENT GMP CONFORMANCE

NSF/IPEC/ANSI 363



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