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BioPharm INTERNATIONAL

May 2021

The Science & Business of Biopharmaceuticals

Working with contractors to ensure quality

The COVID-19 pandemic has required pharmaceutical companies and contract manufacturing organizations (CMOs)/contract development and manufacturing organizations (CDMO) to quickly work to develop and produce vaccines to prevent COVID-19 and medicines to treat the patients who get sick with the virus. Part of this process is the regulatory approval of manfucturing lines and facilities used to manufacture these products. How can sponsor companies and contract organizations ensure their facilities are up to standard for the manufacture of COVID-19 and other medicines?

CMOs and CDMOs that don't have the capacity to validate drug license applications for their manufacturing lines will often hire consultants to assist in pre-approval inspections (PAIs) and pre-licensure inspections (PLI), according to Edgar Guerzon, senior managing consultant at Tunnell Consulting. And technology transfer from the sponsor company to the CMO/CDMO facility is key, says Guerzon. "This site must be designed not only to be able to produce a scaled-up version of that sponsor's product, but be versatile enough to accommodate other sponsors' products. The technology-transfer report must have very explicit documentation, which demonstrates sound, logical, scientific reasoning that when scaled up, the product will be safe and efficacious to the patient," says Guerzon.

To verify that CMOs/CDMOs are following current good manufacturing practices, sponsor companies should perform process mapping and risk analysis, says Guerzon. Failure modes and effect analysis (FMEA) can identify failure in manufacturing and testing processes, according to Guerzon. "Then you plan to either eliminate the occurrence of failure or minimize its effect. Basically, determine all scenarios where something may go wrong and have a plan to address them. There should be separate FMEAs for process, testing, and equipment; these are live documents and updated as necessary," he says.

—Susan Haigney