Consultants Update

COVID-19

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Discussion Topics

- New FDA Guidance – COVID-19 – Drug Manufacturers

FDA Drug Manufacturer Guidance

- Good Manufacturing Practice Considerations for Responding to COVID-19 Infection in Employees in Drug and Biological Products Manufacturing - Guidance for Industry June 2020
- Implemented without comment period
- https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders

FDA Drug Manufacturer Guidance

- Applicable during the COVID-19 health emergency… however… “within 60 days following the termination of the public health emergency, FDA intends to revise and replace this guidance…”

Manufacturing Controls

- For drug products, 21 CFR 211.28(d), "Personnel responsibilities," requires that:
  - Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products.

Manufacturing Controls

- Drug manufacturers should vigilantly monitor employees for symptoms of COVID-19 infection
  - who perform drug manufacturing functions and have been exposed to others with confirmed or suspected COVID-19
- Employees must be excluded from drug manufacturing areas who
  - test positive for COVID-19 (regardless of whether they have symptoms)
  - have symptoms of COVID-19
- FDA recommends that such employees should not return to work in such areas until the CDC's criteria to discontinue home isolation are met, in consultation with health care providers.

Manufacturing Controls

- Drug product manufacturers must ensure that employees practice good sanitation and health habits, in accordance with 21 CFR 211.28(b) – or the drug is considered adulterated.

Risk Management

- Evaluate
  - The adequacy of the CGMP controls already in place to protect materials, components, drug container closures, in-process materials, and/or drugs from sick employees in the context of this new coronavirus.
  - Facility and equipment cleaning and sanitation and other controls that ensure materials, components, drug product containers and closures, in-process materials, and drug products are safe and meet their quality requirements

Specific Recommendations

- Clean and sanitize nonproduction areas (such as offices, elevators, break rooms, changing rooms, and restrooms) more frequently.
- Update existing procedures to institute more frequent cleaning, sanitization, and/or sterilization of surfaces in the production areas, particularly surfaces that are contacted frequently, such as door handles, equipment latches, bench/counter tops, and control panels. Special attention should be paid to sanitizing/sterilizing equipment and product-contact surfaces.
- Consider expanding existing procedures to include using gloves, face masks, and/or gowning where such measures were not previously required.

Specific Recommendations

- Consider further restrictions on employee access to any manufacturing area, beyond that required by CGMP regulations and recommended by Agency guidance and normal practice, to limit the possibility of contamination.
- If a potential or actual viral contamination event is identified, drug manufacturers should promptly clean, disinfect, sanitize, and if necessary, sterilize affected equipment, surfaces, production areas, and facilities, before resuming manufacturing.
- If supplies of single-use masks and other garb used to control contamination during manufacturing are low, they should be prioritized for use in sterile manufacturing operations.

QCU – Documented Evaluations

- Ensure that all evaluations of the production controls (including risk assessments), follow-up, and changes are approved by the manufacturer's quality unit and documented

COVID-19 Impact on Drug Safety, Quality, and Disposition

- Drug manufacturers should determine if SARS-CoV-2 could adversely affect the safety or quality of their materials, components, drug product containers and closures, in-process materials, and drugs if they were to become contaminated with the virus.
- Lots or batches of components, drug product containers and closures, in-process materials, and/or drug products determined to be adversely affected in terms of safety and quality must not be released – quarantine.

COVID-19 Impact on Drug Safety, Quality, and Disposition

- Drug product manufacturers must ensure that all evaluations (including risk assessments) to determine if drug safety or quality were adversely affected, as well as any follow-up and changes, are approved by the manufacturer's quality unit and documented within the manufacturer's quality management system, in accordance with 21 CFR 211.22, 21 CFR 211.100, and 21 CFR 212.20.

Maintaining the Drug Supply

- Follow CDC guidance
- Direct workers who have symptoms (e.g., fever, cough, or shortness of breath) to notify their supervisors and stay home.
- Social Distancing at work
- Contingency plans if absenteeism is high
- Notify FDA if a supply disruption is likely

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