U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Drugs

Questions and Answers on Current Good Manufacturing Practices, Good Guidance Practices, Level 2 Guidance - Production and Process Controls

1. Do the CGMPs require a firm to retain the equipment status identification labels with the batch record or other file? Assuming each major piece of equipment has a unique "Cleaning and Use Log" that is adequately retained, is it acceptable to discard these 'quick reference' equipment labels?

The CGMP regulations for finished pharmaceuticals require the retention of cleaning and use logs for non-dedicated equipment, but no similar requirement exists for retaining what are intended to be "quick reference" or temporary status labels. Examples of these kinds of status labels include "mixing lot ###"; "clean, ready for use as of d/M/y"; "not clean." We see no value in the retention of such labels in addition to the required equipment log or batch record documentation. The labels serve a valuable, temporary purpose of positively identifying the current status of equipment and the material under process. Any status label should be correct, legible, readily visible, and associated with the correct piece of equipment. The information on the temporary status label should correspond with the information recorded in the equipment cleaning and use log, or the previous batch record for non-dedicated equipment.

Labels are merely one way to display temporary status information about a piece of equipment. It is considered acceptable practice to display temporary equipment status information on dry-erase boards or chalkboards. And it would be appropriate for an FDA investigator to verify that the information on a temporary status label is consistent with the log.

References:

- 21 CFR 211.182: Equipment cleaning and use log
- 21 CFR 211.105: Equipment identification

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2. Can containers, closures, and packaging materials be sampled for receipt examination in the warehouse?

Yes. Generally, we believe that sampling in a typical drug manufacturing facility warehouse would not represent a risk to the container/closure or affect the integrity of the sample results. But whether the act of collecting a sample in the warehouse violates the CGMPs requirement that containers "be opened, sampled, and sealed in a manner designed to prevent contamination of their contents..." will depend on the purported quality characteristics of the material under sample and the warehouse environment. For container/closures purporting to be sterile or depyrogenated, sampling should be under conditions equivalent to the purported quality of the material: a warehouse environment would not suffice (see 211.94 and 211.113(b)). This is to preserve the fitness for use of the remaining container/closures as well as ensure sample integrity, if they are to be examined for microbial contamination. At a minimum, any sampling should be performed in a manner to limit exposure to the environment during and after the time samples are removed (i.e., wiping outside surfaces, limiting time that the original package is open, and properly resealing original package). Well-written and followed procedures are the critical elements.

Note that the CGMPs at 211.84 permit a manufacturer to release for use a shipment of containers/closures based on the supplier's certificate of analysis and a visual identification of the containers/closures. Once a supplier's reliability has been established by validation of their test results, a

manufacturer could perform the visual examination entirely in the warehouse.

References:

- 21 CFR 211.84: Testing and approval or rejection of components, drug product containers, and closures
- 21 CFR 211.94: Drug product containers and closures
- 21 CFR 211.113(b): Control of microbiological contamination
- 21 CFR 211.122: Materials examination and usage criteria

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3. A firm has multiple media fill failures. They conducted their media fills using TSB (tryptic soy broth) prepared by filtration through 0.2 micron sterilizing filter. Investigation did not show any obvious causes. What could be the source of contamination?

A firm recently had multiple media fill failures. The media fill runs, simulating the filling process during production, were conducted inside an isolator. The firm used TSB (non-sterile bulk powder) from a commercial source, and prepared the sterile solution by filtering through a 0.2 micron sterilizing filter. An investigation was launched to trace the source of contamination. The investigation was not successful in isolating or recovering the contaminating organism using conventional microbiological techniques, including the use of selective (e.g., blood agar) and nonselective (e.g., TSB and tryptic soy agar) media, and examination under a microscope. The contaminant was eventually identified to be *Acholeplasma laidlawii* by using 16S rRNA gene sequence. The firm subsequently conducted studies to confirm the presence of *Acholeplasma laidlawii* in the lot of TSB used. Therefore, it was not a contaminant from the process, but from the media source.

Acholeplasma laidlawii belongs to an order of mycoplasma. Mycoplasma contain only a cell membrane and have no cell wall. They are not susceptible to beta-lactams and do not take up Gram stain. Individual organisms are pleomorphic (assume various shape from cocci to rods to filaments), varying in size from 0.2 to 0.3 microns or smaller. It has been shown that *Acholeplasma laidlawii* is capable of penetrating a 0.2 micron filter, but is retained by a 0.1 micron filter (see Sundaram, et al.). *Acholeplasma laidlawii* is known to be associated with animal-derived material, and microbiological media is often from animal sources. Environmental monitoring of mycoplasma requires selective media (PPLO broth or agar).

Resolution:

For now, this firm has decided to filter prepared TSB, for use in media fills, through a 0.1 micron filter (note: we do not expect or require firms to routinely use 0.1 micron filters for media preparation). In the future, the firm will use sterile, irradiated TSB when it becomes available from a commercial supplier. (Firm's autoclave is too small to permit processing of TSB for media fills, so this was not a viable option.) The firm will continue monitoring for mycoplasma and has revalidated their cleaning procedure to verify its removal. In this case, a thorough investigation by the firm led to a determination of the cause of the failure and an appropriate corrective action.

References:

- 21 CFR 211.113: Control of microbiological contamination
- 21 CFR 211.72: Filters
- 21 CFR 211.84(d)(6): Testing and approval or rejection of components, drug product container, and closures
- Sundaram, S., Eisenhuth, J., Howard, G., Brandwein, H. Application of membrane filtration for removal of diminutive bioburden organisms in pharmaceutical products and processes. PDA J. Pharm. Sci. Technol. 1999 Jul-Aug; 53(4): 186-201.
- Kong, F., James, G., Gordon, S., Zekynski, A., Gilbert, G.L. Species-specific PCR for identification of common contaminant mollicutes in cell culture. Appl. Environ. Microbiol. 2001 Jul; 67(7): 3195-200.
- Murray, P., Baron, E., Pfaller, M., Tenover, F., Yolken, R. Manual of Clinical Microbiology ASM Press, Sixth Edition.

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http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm096102.htm

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4. Some products, such as transdermal patches, are made using manufacturing processes with higher in-process material reject rates than for other products and processes. Is this okay?

Maybe. It depends on the cause and consistency of the reject rate. Many transdermal patch manufacturing processes produce more waste (i.e., lower yield from theoretical) than other pharmaceutical processes. This should not of itself be a concern. The waste is usually due to the cumulative effect of roll splicing, line start-ups and stoppages, roll-stock changes, and perhaps higher rates of in-process sampling. This is most pronounced for processes involving lamination of rolls of various component layers. Roll-stock defects detected during adhesive coating of the roll, for example, can often only be rejected from the roll after final fabrication/lamination of the entire patch, which contributes to the final process waste stream.

We expect that validated and well-controlled processes will achieve fairly consistent waste amounts batch-to-batch. Waste in excess of the normal operating rates may need (see 211.192) to be evaluated to determine cause (e.g., due to increase in sampling or higher than normal component defects... or both) and the consequences on product quality assessed. We've seen a small number of cases where unusually high intra-batch rejects/losses were due to excessive component quality variability and poorly developed processes.

References:

- 21 CFR 211.100: Written procedures; deviations
- 21 CFR 211.103: Calculation of yield
- 21 CFR 211.110: Sampling and testing of in-process materials and drug products
- 21 CFR 211.192: Production record review

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5. **Do CGMPs require three successful process validation batches before a new active pharmaceutical ingredient (API) or a finished drug product is released for distribution?**

No. Neither the CGMP regulations nor FDA policy specifies a minimum number of batches to validate a manufacturing process. The current industry guidance on APIs (see ICH Q7A for APIs) also does not specify a specific number of batches for process validation.

FDA recognizes that validating a manufacturing process, or a change to a process, cannot be reduced to so simplistic a formula as the completion of three successful full scale batches. The agency acknowledges that the idea of three validation batches has become prevalent, in part due to

language in its own guidance documents. However, FDA is now clarifying current expectations on process validation. The 1987 *Guideline of General Principles of Process Validation* is currently being revised to address this issue. The emphasis for demonstrating validated processes is placed on the manufacturer's process design and development studies in addition to its demonstration of reproducibility at scale, a goal that has always been expected.

However, a minimum number of conformance (a.k.a. validation) batches necessary to validate the manufacturing processes is not specified. The manufacturer is expected to have a sound rationale for its choices in this regard. The agency encourages the use of science based approaches to process validation.

In March 2004, FDA revised the Compliance Policy Guide (CPG) (Sec. 490.100) on *Process Validation Requirements for Drug Products and Active Pharmaceutical Ingredients Subject to Pre-Market Approval*. The CPG describes the concept that, after having identified and establishing control of all critical sources of variability, conformance batches are prepared to demonstrate that under normal conditions and operating parameters, the process results in the production of acceptable product. Successful completion of the initial conformance batches would normally be expected before commercial distribution begins, but some possible exceptions are described in the CPG. For example, although the CPG does not specifically mention concurrent validation for an API in short supply, the agency would consider the use of concurrent validation when it is necessary to address a true short-supply situation, and if the concurrent validation study conforms to the conditions identified in the CPG (See paragraph 4. a-c).

The conditions outlined in the CPG include expanded testing for each batch intended to address a short-supply situation. Expanded testing, conducted according to an established validation protocol could provide added assurance that the batch meets all established and appropriate criteria before the API is used in the finished drug product. Additionally, confidence in the API manufacturing process may be gained by enhanced sampling (larger sample size representative of batch) and perhaps the testing of additional attributes. Validated analytical methods are needed for testing every batch, including validation batches. The agency would also expect the manufacturer to use a validation protocol which includes a review and final report after multiple batches are completed, even though the earlier batches may have been distributed or used in the finished drug product.

References:

- 21 CFR 211.100: Written procedures; deviations
- 21 CFR 211.110: Sampling and testing of in-process materials and drug products
- CPG 490.100 Process Validation Requirements for Drug Products and Active Pharmaceutical Ingredients Subject to Pre-Market Approval.
- ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients

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6. Is it generally acceptable from a cGMP perspective for a manufacturer of sterile drug products produced by aseptic processing to rely solely on ISO 14644-1 and ISO 14644-2 when qualifying their facility?

No. It is generally not acceptable from a current good manufacturing practice ("cGMP") perspective for a manufacturer of sterile drug products produced by aseptic processing to rely solely on *ISO 14644-1 Part 1: Classification of Air Cleanliness* ("14644-1") and *ISO 14644-2 Part 2: Specifications for Testing and Monitoring to Prove Compliance with ISO 14644-1* ("14644-2") when qualifying their facility. Rather, a manufacturer of sterile drug products produced by aseptic processing should use these ISO standards in combination with applicable FDA regulations, guidance and other relevant references to ensure a pharmaceutical facility is under an appropriate state of control. Consequently, appropriate measures augmenting ISO's recommendations (e.g., with microbiological data) would likely be expected for a firm to meet or exceed CGMP in a pharmaceutical facility.

Please understand that 14644-1 and 14644-2 have superseded *Federal Standard 209E, Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones* ("Federal Standard 209E"). In November 2001, the U.S. General Services Administration canceled Federal Standard 209E.

While not FDA regulations or FDA guidance, the Agency believes 14644-1 and 14644-2 are useful in facilitating the international harmonization of industrial air classification for non-viable particle cleanliness in multiple industries (e.g., computer, aerospace, pharmaceutical). As such, FDA adopted these particle cleanliness ratings in the 2004 guidance for industry *Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice*. However, due to the unique aspects of producing sterile drug products by aseptic processing (e.g., microbiological issues) an aseptic processing manufacturer should not rely solely on 14644-1 and 14644-2 when qualifying their facility.

References:

- U.S. Food and Drug Administration website.
- International Organization for Standardization website.
- ISO 14644-1 Part 1*: Classification of Air Cleanliness*.
- ISO 14644-2 Part 2: *Specifications for Testing and Monitoring to Prove Compliance with ISO 14644-1*.
- Guidance for Industry: *Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice* (2004).
- Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Part 211).

Contact Information:

Division of Manufacturing and Product Quality (HFD-320): CGMP Subject Contacts
http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm096102.htm

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7. In 2004, FDA issued a guidance entitled "PAT - A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance" that encouraged industry to modernize manufacturing through enhancements in process control. How can I implement PAT (Process Analytical Technology)?

The objective of FDA's PAT program is to facilitate adoption of PAT. In our 2004 guidance, we discuss FDA's collaborative approach to promote industry uptake of new and beneficial technologies that modernize manufacturing operations and enhance process control. FDA recognizes that firms should be encouraged to promptly implement new systems that improve assurance of quality and process efficiency. Accordingly, our approach to PAT implementation is risk based, and includes multiple options:

1. PAT can be implemented under the facility's own quality system. CGMP inspections by the PAT Team or PAT certified Investigator can precede or follow PAT implementation.

2. As another quality system implementation option, FDA invites manufacturers to request a preoperational review of their PAT manufacturing facility and process by the PAT Team (see ORA Field Management Directive No.135).

3. A supplement (CBE, CBE-30 or PAS) can be submitted to the Agency prior to implementation, and, if necessary, an inspection can be performed by a PAT Team or PAT certified Investigator before implementation. This option should be used, for example, when an endproduct testing specification established in the application will be changed.

4. A comparability protocol can be submitted to the Agency outlining PAT research, validation and implementation strategies, and time lines. Following collaborative review of the general strategy outlined in the comparability protocol, the regulatory pathway can include implementation

under the facility's own quality system, a pre-operational review, CGMP inspections (either before or after PAT implementation), a combination of these, or another flexible approach.

Manufacturers should evaluate and discuss with the Agency the most appropriate option for PAT implementation. For products regulated by the CDER, contact the Process Analytical Technology Team with any questions.

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8. How do I contact CDER's Process Analytical Technology Team?

Manufacturers are encouraged to contact the team via *email* regarding any PAT questions at: PAT@cder.fda.gov

To contact our PAT Team via *mail*, please see the PAT Web page (under the section "Contact Us") for our new mailing address at White Oak.

All correspondence should be identified clearly as "Process Analytical Technology" or "PAT."

Please also refer to the Web page to keep abreast of the latest information on PAT.

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9 . How do I contact CBER's Process Analytical Technology Team?

Manufacturers should contact the appropriate review division in CBER to discuss applicability of PAT to CBER-regulated products.

References:

"PAT - A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance"

Contact Information:

- PAT Questions (CDER): PAT@cder.fda.gov
- PAT Team Members

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10. What is the acceptable media fill frequency in relation to the number of shifts? Normally, media fills should be repeated twice per shift per line per year. Is the same frequency expected of a process conducted in an isolator?

A firm's justification for the frequency of media fills in relation to shifts should be risk-based, depending on the type of operations and the media fill study design. For *closed*, highly automated systems run on multiple shifts, a firm with a rigorous media fill design may be justified to conduct a lower number of total media fill runs. Such a program can be appropriate provided that it still assures performance of media fills for each aseptic processing line at least semi-annually. The 2004 guidance for industry on *Sterile Drug Products Produced by Aseptic Processing* states that "[A]ctivities and interventions representative of each shift, and shift changeover, should be incorporated into the design of the semi-annual qualification program." In addition, the EU Annex 1, *Manufacture of Sterile Medicinal Products,* states that "Normally, process simulation tests should be repeated twice a year per shift and process."

Certain modern manufacturing designs (isolators and "closed vial" filling) afford isolation of the aseptic process from microbiological contamination risks (e.g., operators and surrounding room environment) throughout processing. For such *closed* systemsï¼`, if the design of the processing equipment is robust and the extent of manual manipulation in the manufacturing process is minimized, a firm can consider this information in determining its media fill validation approach. For example, it is expected that a conventional aseptic processing line that operates on two shifts be evaluated twice per year per shift, and culminate in four media fills. However, for aseptic filling conducted in an isolator over two shifts, it may be justified to perform fewer than four media fill runs per year, while still evaluating the line semi-annually to assure a continued state of aseptic process control. This lower total number of media fill runs would be based on sound risk rationale and would be subject to re-evaluation if contamination issues (e.g., product non-sterility, media fill failure, any problematic environmental trends) occur.

ï¼` This does not apply to RABS (Restricted Access Barrier Systems)

References:

1. 21 CFR 211.63, 211.65, and 211.67 address, respectively, "Equipment design, size, and location," "Equipment construction," and "Equipment cleaning and maintenance."

2. 21 CFR 211.84(c)(3) states that "Sterile equipment and aseptic sampling techniques shall be used when necessary."

3. 21 CFR 211.113(b) states that "Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and any sterilization process."

4. FDA Guidance for Industry *Sterile Drug Products Produced by Aseptic Processing* (2004)

5. EU Annex 1, *Manufacture of Sterile Medicinal Products* (2003)

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http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm096102.htm

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11. Why is the FDA concerned about human topical antiseptic drug products?

FDA has identified several incidents of objectionable microbial contamination of topical antiseptic drug products (e.g., alcohol pads or swabs used to prepare the skin prior to an injection). Microbial contamination may be caused by substandard manufacturing practices and the agency is concerned about safety risks, such as from infection, associated with this contamination.

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12. What specific current good manufacturing practice (CGMP) regulations might be useful to manufacturers of topical antiseptic drug products?

Section 501(a) (2) (B) of the Federal Food, Drug, and Cosmetic Act requires all drugs to be manufactured in conformance with CGMP. The CGMP regulations in 21 CFR Parts 210 and 211 for finished pharmaceuticals apply equally to over-the-counter (OTC) and prescription (Rx) drug products.[1]

The CGMP regulations provide the minimum legal requirements for conducting reliable operations.[2] Some relevant CGMP regulations, with a brief description, are given below:

Manufacturing Design and Control – CGMP Requirements and Recommended Guidance for Manufacturers

- **Design manufacturing facilities (21 CFR 211.42) and processes (see below) to prevent microbial contamination** :
    - **For non-sterile drug products –** establish control procedures to monitor output and validate processes to include bioburden testing (21 CFR 211.110 (a) (6)), 211.111) and establish and follow written procedures designed to prevent the introduction of objectionable microorganisms (211.113(a)).
    - **For sterile drug products**[3] **-** establish and follow written procedures designed to prevent microbial contamination (211.113(b)).
- **Conduct process validation studies**[4] to ensure acceptable output (e.g., with topical antiseptics, particularly product microbiological quality) (211.110(a). Implement and validate needed changes when deficient manufacturing steps, equipment, or raw materials may be adversely affecting process control.
- **Ensure that operating procedures** will consistently produce a quality product (211.100). Review and evaluate any deviations or discrepancies documented during manufacturing and testing to determine if a product lacks assurance of sterility (for sterile antiseptics) or may be contaminated with objectionable microorganisms (for non-sterile antiseptics). Document and implement any corrective actions deriving from the evaluation (211.192).
- **Ensure that all equipment,** including water systems, is clean, sanitary, operates consistently, and is suitable for its intended use (211.63, 211.65, 211.67, and 211.68).
- **Establish and follow in-process bioburden testing** procedures to help monitor in-process control, including understanding the bioburden challenge to a final sterilization process (211.110(a)(6)).

Components, In-process Materials, Container/Closure and Finished Product Testing - CGMP Requirements for Manufacturers

- **Establish appropriate written testing standards/specifications and sampling plans** for components, in-process materials, containers/closures, and finished products (211.160).
- **Establish procedures for testing** and approval or rejection of components, drug product containers, and closures (211.80). Test each lot of a drug product component and container/closure, including those that may be vulnerable to microbiological contamination (211.84)(d)(4-5), including applicator material (e.g., cotton pads) and water used as an ingredient in the product.
- **Conduct appropriate microbiological tests** before a batch disposition decision is made. Test each batch of a sterile product for sterility (211.167). Test each batch of a non-sterile product to ensure absence of objectionable microorganisms (211.165(b)).

Management[5,6]

The CGMPs require that the management of a manufacturing facility maintains a well-functioning quality system, which includes an effective quality unit vested with the responsibilities and authorities required under CGMP (211.22).

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13. How can manufacturers assess and address the risk of microbiological contamination of topical antiseptics?

Since there are potentially many different root causes of product contamination by microorganisms, it is imperative that manufacturers perform a manufacturing risk assessment to understand manufacturing failure modes and implement prevention measures.

In addition, any risk assessment approach should be informed by an understanding of the microbial contamination vulnerabilities of the concerned product. For example, some product considerations for manufacturers include, but are not limited to:

- Determine the types of microbes that might survive or thrive in your products. Provide additional controls and testing based on the output of the risk assessment to ensure product quality.
- Ensure that your microbial recovery methods are capable of detecting the types of microbes that may affect product quality.
- Evaluate risk of contamination from components, including during component production, storage, or due to the intrinsic risk from source materials. Consider all possible sources of microbial contamination, including the following:
    - Components or products stored in open bins can be at risk for contamination by spore-forming microbes, such as *Bacillus cereus,*[7,8] as well as by *Serratia* species and other worrisome airborne microbes. Manufacturing areas exposed to windy or poor HVAC conditions may increase the potential for this environmental contamination risk.
    - Some materials, especially from natural sources, may have high or objectionable intrinsic bioburden.
    - Water quality can pose a significant risk, as most antiseptics include water as a key ingredient. Contaminated purified water has been the root cause of multiple recalls of antiseptics, including instances of antiseptics contaminated with *Burkholderia* (previously *Pseudomonas*) *cepacia*, an opportunistic pathogen.
    - Unsanitary practices or sources
    - When manufacturing in areas with high humidity, molds can be of special concern.

References:

1. Compliance Policy Guide Sec. 450.100 *CGMP Enforcement Policy - OTC vs. Rx Drugs* (http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074387.htm)
2. Code of Federal Regulations (CFR), Title 21, Part 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=211)
3. FDA Guidance for Industry on *Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice* (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070342.pdf)
4. FDA Guidance for Industry on *Process Validation* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070336.pdf
5. FDA Guidance for Industry on *ICH Q9 – Quality Risk Management* (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073511.pdf)

6. FDA Guidance for Industry on *ICH Q10 – Pharmaceutical Quality System*
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073517.pdf
7. FDA News Release - *FDA reminds health care professionals about safe use of non-sterile alcohol prep pads* (2/1/2011)
(http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm241750.htm)
8. CDC Morbidity and Mortality Weekly Report (MMWR) - *Contamination of Alcohol Prep Pads with* Bacillus cereus *Group and* Bacillus *Species*
(http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6011a5.htm)

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