QSTREAM

Good Manufacturing Practice 2024

Description: The purpose of this Qstream is to test and reinforce knowledge related to Good Manufacturing Practice

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DECKS	QUESTIONS	CREATED	U
Good Manufacturing Practice	13	27 Jul 2022 1:36 PM Peter Murphy	2 F

Inspection protocol

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

Joseph is a Food and Drug Administration (FDA) agent who is inspecting ACME labs. In doing so, he needs to make sure he arrives at ACME:

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No
Timed Bonus: No

AUTHORS

Missing Author

CREATED

Peter Murphy
July 27th, 2022 @ 12:52 PM

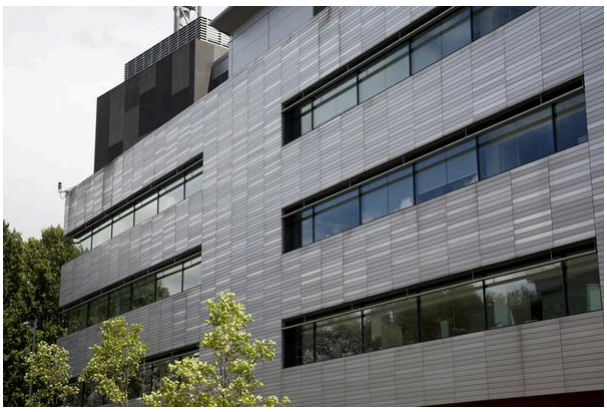
UPDATED

Peter Murphy
November 17th, 2023 @ 12:28 PM

TOPICS

GMP - Inspections

Question



NO IMAGE DESCRIPTION

Joseph is a Food and Drug Administration (FDA) agent who is inspecting ACME labs. In doing so, he he arrives at ACME:

SELECT 1 ANSWER

- ✓ Without prior announcement
- ✗ With 24 hours verbal anr
- ✗ With 24 hours written announcement
- ✗ With 48 hour written or v

Answer explanation

NO IMAGE DESCRIPTION

According to the 2014 General Inspection Protocol, Joseph needs to arrive unannounced at the facil
there, he must ask for the most responsible person, show his credentials, issue a written *Notice of I*
state the inspection's objective.

LEARN MORE:

Approaches to GMP Inspection *(15-minute FDA slide deck)*

Explore details about the inspection process.

ADDITIONAL INFORMATION:

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufactu

https://www.fda.gov/media/89231/download

Inspection Rigor

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

As a Food and Drug Administration (FDA) agent, Mary plans to visit Pacific Pharmaceuticals for a routine cGMP (Current Good Manufacturing Practice...

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No
Timed Bonus: No

AUTHORS

Missing Author

CREATED

Peter Murphy
July 27th, 2022 @ 12:54 PM

UPDATED

Peter Murphy
November 17th, 2023 @ 12:28 PM

TOPICS

Question

NO IMAGE DESCRIPTION

As a Food and Drug Administration (FDA) agent, Mary plans to visit Pacific Pharmaceuticals for a rc
Good Manufacturing Practice) inspection. Pacific Pharmaceuticals has had three inspections before
compliance violations. Their business has been thriving, and they have expanded their production fa

With this in mind, what type of inspection should Mary conduct?

SELECT 1 ANSWER

- ✓ Full
- ✗ Abbreviated

GMP - Inspections

Minimal

Answer explanation

NO IMAGE DESCRIPTION

Mary should conduct a full inspection because there have been significant changes to Pacific Pharm last inspection - namely the expansion of their production facility. A full inspection would also be w there's an initial establishment inspection or a history of inspection violations.

Mary would be able to perform an abbreviated inspection if there was:

- A good history
- No major changes to operations
- No pattern of recalls and/or problems

ADDITIONAL INFORMATION:

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufactu

https://www.fda.gov/media/89231/download

Quality problem areas

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

According to the Food and Drug Administration (FDA), the top quality problem areas most associated with regulatory action regarding Current Good Manufacturing...

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No
Timed Bonus: No

AUTHORS

Missing Author

CREATED

Peter Murphy
July 27th, 2022 @ 1:18 PM

UPDATED

Peter Murphy

Question

NO IMAGE DESCRIPTION

According to the Food and Drug Administration (FDA), the top quality problem areas most associat action regarding Current Good Manufacturing Practices (cGMPs) include which of the following?

SELECT 1 ANSWER

November 17th, 2023 @ 12:28 PM

TOPICS

GMP - Inspections

- ✓ Investigating and correcting discrepancies or defects
- ✗ Micro-controls for sterile
- ✗ Presence of foreign substances
- ✗ Marketing without an app Application (NDA)

Answer explanation

NO IMAGE DESCRIPTION

The top five quality problem areas most associated with regulatory action from not following Curre Manufacturing Practice (cGMPs) include:

- Investigating and correcting discrepancies or defects
- Micro-controls for sterile and non-sterile
- Stability program
- Process design and qualification (validation)
- Establishing and following sound tests and sampling plans

ADDITIONAL INFORMATION:

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufactu

https://www.fda.gov/media/89231/download

Risk-based framework

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

The Food and Drug Administration (FDA) uses a risk-based framework for prioritizing sites for inspection to ensure compliance with Good Manufacturing...

Question

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No
Timed Bonus: No

AUTHORS

Missing Author

CREATED

Peter Murphy

July 27th, 2022 @ 1:19 PM

UPDATED

Peter Murphy
November 17th, 2023 @ 12:28 PM

TOPICS

GMP - Inspections

NO IMAGE DESCRIPTION

The Food and Drug Administration (FDA) uses a risk-based framework for prioritizing sites for inspe
compliance with Good Manufacturing Practices (GMPs). This framework rates the risk potential bas

SELECT 3 ANSWERS

- [x] Products
- [x] Processes
- [x] Facilities
- [ ] Management

Answer explanation

NO IMAGE DESCRIPTION

The goal of using a risk-based framework is to ensure that Food and Drug Administration (FDA) res
effectively and efficiently to prioritize addressing the most significant risks to public health.

In the context of pharmaceutical quality, the level of risk depends on the potential harm associated
products. Factors that determine this risk include:

- Types of products that are produced
- Types of processes used in the manufacturing and processing
- Type of facility that is used

ADDITIONAL INFORMATION:

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufactu

https://www.fda.gov/media/89231/download

Flexible system design

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

Current Good Manufacturing Practices (cGMPs) provide for _____ systems that assure the proper design, monitoring, and control of manufacturing processes...

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No
Timed Bonus: No

AUTHORS

Missing Author

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Peter Murphy
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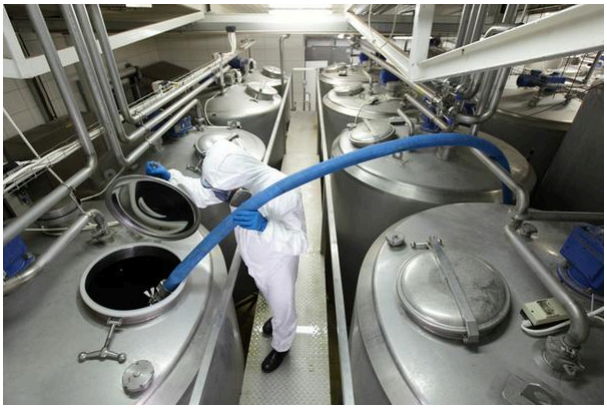
UPDATED

Peter Murphy
November 17th, 2023 @ 12:28 PM

TOPICS

GMP - Why Use GMPs?

Question



NO IMAGE DESCRIPTION

Current Good Manufacturing Practices (cGMPs) provide for _____ systems that assure the proj
monitoring, and control of manufacturing processes and facilities.

SELECT 1 ANSWER

- ✓ Flexible
- ✗ Inflexible
- ✗ Permanent
- ✗ Temporary

Answer explanation

NO IMAGE DESCRIPTION

Current Good Manufacturing Practices (cGMPs) requirements were designed to be flexible to allow
to determine individually how best to implement the necessary procedures and controls at their fac
in the cGMPs allows companies to use the latest innovations, procedures, and equipment to achieve
thus a competitive advantage) through continuous improvement.

The "c" in cGMP addresses the use of systems and equipment that are current. What may have bee
preventing contamination or manufacturing errors a decade ago may not be adequate by current inc

ADDITIONAL INFORMATION:

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufactu

https://www.fda.gov/media/89231/download

Why are GMPs important?

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

Amelia watched a news report about a brand of ibuprofen that was being recalled. Although she didn't catch the company's name, she called the toll-free number...

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No
Timed Bonus: No

AUTHORS

Missing Author

CREATED

Peter Murphy
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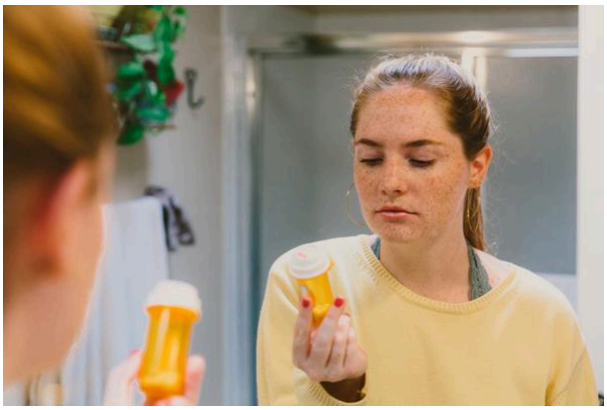
Peter Murphy
November 17th, 2023 @ 12:28 PM

TOPICS

GMP - Why Use GMPs?

Question



NO IMAGE DESCRIPTION

Amelia watched a news report about a brand of ibuprofen that was being recalled. Although she di
company's name, she called the toll-free number of the manufacturer of her brand of ibuprofen to fi
customer services representative told Amelia that it was a different company and assured her that t
safe and effective.

**When Amelia asked for proof, the representative replied that they adhere to Good Manufacturir
which ensure that their:**

SELECT 3 ANSWERS

- ✓ Facilities are in good condition
- ✓ Equipment is properly ma calibrated
- ✗ Employees all have college degrees
- ✓ Processes are reliable an

Answer explanation

NO IMAGE DESCRIPTION

Amelia knows she is unable to detect that a drug product like ibuprofen is either safe or works as in
sight, touch, or smell. Although Good Manufacturing Practices (GMPs) require testing, testing alone
consistent quality. This is because testing only samples a very small fraction (often less than 0.01%
batch. Therefore, GMPs also address manufacturing conditions. Drugs must be manufactured under
practices to assure that quality is built into the design and manufacturing process at every stage.

ADDITIONAL INFORMATION:

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufactu

https://www.fda.gov/media/89231/download

Why use GMPs?

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

Marcus and Victoria are chatting about work during their break from the production line at a pharmaceutical company. Marcus complains about the cross-checking...

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No
Timed Bonus: No

AUTHORS

Missing Author

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Peter Murphy
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Peter Murphy
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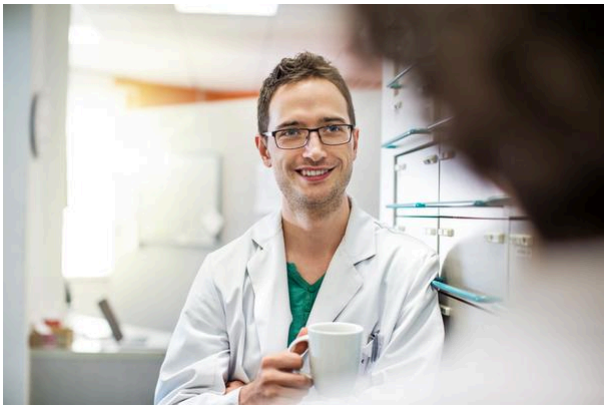
TOPICS

GMP - Why Use GMPs?

Question



NO IMAGE DESCRIPTION

Marcus and Victoria are chatting about work during their break from the production line at a pharma
Marcus complains about the cross-checking and reporting required to comply with Good Manufactu
(GMPs). He suggests their company could save a lot of money if they just focused on manufacturing
quality control and reporting regulations.

Victoria replies that their company would actually lose a lot of money if they didn't follow GMP

SELECT 3 ANSWERS

- ✓ Customers could get sick or die if the medicines they used from their company were of poor quality, which would result in expensive lawsuits.
- ✓ Many countries only acce of medicines that have be following GMPs.
- ✓ In the long run, it is more expensive to find mistakes after they've occurred than preventing them with GMPs in the first place.
- ✗ Following other procedur Health Organization (WH time-consuming than foll

Answer explanation

NO IMAGE DESCRIPTION

Although it costs time, money, and effort to follow all of the procedures and guidelines of Good Ma (GMPs), in the long run, prevention is less expensive than finding and addressing mistakes after the

Also, GMPs are often a requirement for selling to external markets since they ensure that quality is example, If a drug has little or none of the claimed ingredients due to poor manufacturing, it will no therapeutic effect. At the very least, this will hurt the brand's image of a quality product and ultima More importantly, it may be a health hazard to consumers, resulting in injury or death.

LEARN MORE:

Find answers to common questions about GMPs by reading this 2-minute article, **Medicines: Good Practices**

ADDITIONAL INFORMATION:

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufactu

https://www.fda.gov/media/89231/download

Adulterated drugs

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

During a staff meeting about unannounced Food and Drug Administration (FDA) inspections, Samuel asks the presenter what happens when a pharmaceutical company...

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No
Timed Bonus: No

AUTHORS

Missing Author

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Peter Murphy
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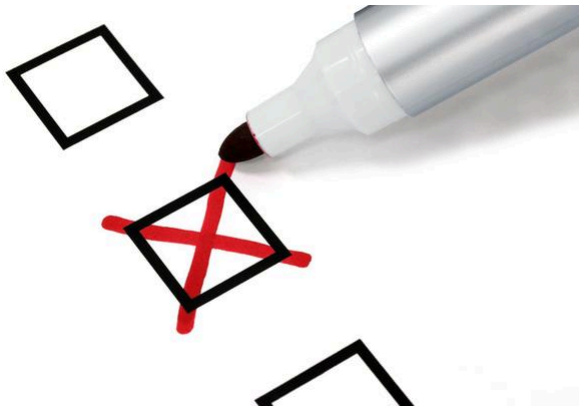
UPDATED

Peter Murphy
November 17th, 2023 @ 12:28 PM

TOPICS

GMP - Violations

Question



NO IMAGE DESCRIPTION

During a staff meeting about unannounced Food and Drug Administration (FDA) inspections, Samu what happens when a pharmaceutical company is found to be out of compliance with Good Manufa (GMPs).

The presenter tells Samuel and the rest of the staff that under the law, the drugs they would m _____.

SELECT 1 ANSWER

- ✓ Adulterated
- ✗ Unadulterated
- ✗ Defective
- ✗ Compromised

Answer explanation

NO IMAGE DESCRIPTION

Adulteration means that a drug was not manufactured under conditions that comply with Good Ma
(GMPs). This does not necessarily mean that there is something wrong with the drug; therefore, the
Administration (FDA) usually advises consumers to seek advice from their health care professionals
changing medications. Ultimately, the company risks the potential loss in sales, customer confidenc
the threat of legal action.

ADDITIONAL INFORMATION:

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufactu

https://www.fda.gov/media/89231/download

Level of compliance

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

Most pharmaceutical manufacturing facilities that are inspected by the Food and Drug Administration (FDA) are found to be _____ compliant with Good...

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No
Timed Bonus: No

AUTHORS

Missing Author

CREATED

Peter Murphy
July 27th, 2022 @ 1:23 PM

UPDATED

Peter Murphy
November 17th, 2023 @ 12:28 PM

TOPICS

Question

NO IMAGE DESCRIPTION

Most pharmaceutical manufacturing facilities that are inspected by the Food and Drug Administratic
be _____ compliant with Good Manufacturing Practice (GMP) regulations.

SELECT 1 ANSWER

- ✓ Fully
- ✗ Partially
- ✗ Minimally
- ✗ Not

GMP - Violations

Answer explanation

NO IMAGE DESCRIPTION

The Food and Drug Administration (FDA) inspects pharmaceutical manufacturing facilities worldwi that manufacture the active ingredients and the finished products. Trained FDA staff follow a stand investigations and find that most facilities are fully compliant with the Good Manufacturing Practice

ADDITIONAL INFORMATION:

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufactu

https://www.fda.gov/media/89231/download

Violations

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

Jessica, a vice president of ACME labs, is discussing with her senior managers how crucial it is for the company to follow Current Good Manufacturing...

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No
Timed Bonus: No

AUTHORS

Missing Author

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Peter Murphy
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Peter Murphy
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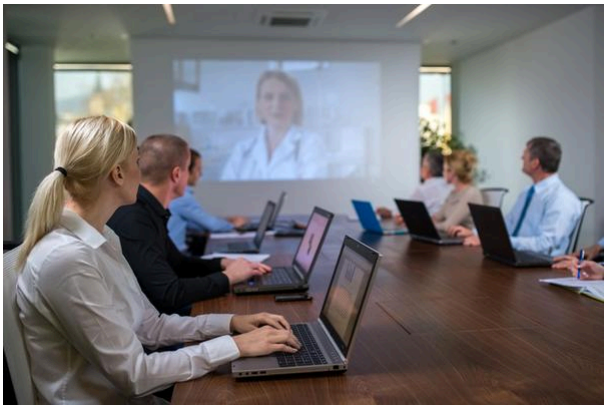
TOPICS

Question



NO IMAGE DESCRIPTION

Jessica, a vice president of ACME labs, is discussing with her senior managers how crucial it is for th Current Good Manufacturing Practices (cGMPs). She explains that there are substantial consequenc to be in violation, including:

SELECT 4 ANSWERS

- ✓ Stopping the distribution or manufacturing of the product
- ✗ Forcing the company to r
- ✓ Seizing or taking possession of the product
- ✓ Filing an injunction with t company to correct the G

GMP - Violations

- [x] Bringing a criminal case against the company

Answer explanation

NO IMAGE DESCRIPTION

Suppose the Food and Drug Administration (FDA) finds a company in violation of Current Good Mar (CGMPs). In that case, they can take actions to prevent the possibility of unsafe and/or ineffective dr consumers. These actions include:

- Stopping the distribution or manufacturing of the product
- Making a recommendation to recall the product. Companies often voluntarily comply with the the FDA cannot force a company to recall a product
- Bringing a seizure or injunction case in court. In a seizure case, FDA officials can take possess and in an injunction case, they can order companies to take corrective steps such as repairing cleanliness, and improving employee training
- Bringing a criminal case against a company and seeking fines and jail time

LEARN MORE:

Facts About the Current Good Manufacturing Practices (cGMPs) *(5-minute article)*

Get a quick overview of the CGMPs from the FDA.

ADDITIONAL INFORMATION:

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufactu

https://www.fda.gov/media/89231/download

Controlling manufacturing

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

Rene was just promoted to Production Manager at ACME labs. As part of her onboarding process, she is reviewing her specific duties, which require a greater...

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No
Timed Bonus: No

AUTHORS

Missing Author

Question

NO IMAGE DESCRIPTION

CREATED

Peter Murphy
July 27th, 2022 @ 1:26 PM

UPDATED

Peter Murphy
November 17th, 2023 @ 12:28 PM

TOPICS

GMP - What is GMP?

Rene was just promoted to Production Manager at ACME labs. As part of her onboarding process, s
specific duties, which require a greater understanding of her company's total operations.

**She knows that ACME labs have robust quality management systems but is surprised to learn t
Manufacturing Practices (GMPs) implemented throughout the organization include:**

SELECT 3 ANSWERS

- [x] Obtaining appropriate quality raw materials
- [x] Establishing and maintair procedures
- [x] Detecting and investigating product quality deviations
- [ ] Using current market rese data in their marketing ar

Answer explanation

NO IMAGE DESCRIPTION

Rene discovers that Good Manufacturing Practices (GMPs) assures the identity, strength, quality, an
products are maintained by requiring businesses that manufacture medications, such as ACME labs
their manufacturing operations. This is accomplished by:

- Establishing strong quality management systems
- Obtaining appropriate quality raw materials
- Establishing and maintaining robust operating procedures
- Detecting and investigating product quality deviations
- Maintaining reliable testing laboratories

ADDITIONAL INFORMATION:

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufactu

https://www.fda.gov/media/89231/download

Definition of GMP

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

GMPs may be referred to as cGMPs, which stands for:_____.

Question

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No

Timed Bonus: No

AUTHORS

Missing Author

CREATED

Peter Murphy
July 27th, 2022 @ 1:27 PM

UPDATED

Peter Murphy
November 17th, 2023 @ 12:28 PM

TOPICS

GMP - What is GMP?

NO IMAGE DESCRIPTION

GMPs may be referred to as cGMPs, which stands for:_____.

SELECT 1 ANSWER

- ✗ Clinical; Good Manufacturing Practices
- ✗ Clinical; Good Manufactu
- ✓ Current; Good Manufacturing Practices
- ✗ Current; Good Manufactu

Answer explanation

NO IMAGE DESCRIPTION

Current Good Manufacturing Practices (cGMPs) are the main regulatory standard for ensuring pharr human pharmaceuticals. Consumers expect that the medicines that they take meet the quality stanc efficacy.

ADDITIONAL INFORMATION:

https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufactu

https://www.fda.gov/media/89231/download

Who needs to follow GMP?

QUESTION TYPE: **CLASSIC** DECK: **GOOD MANUFACTURING PRACTICE**

QUESTION EXCERPT

Question

Sarah is talking with her colleague, Jesse, about Good Manufacturing Practices (GMPs) as they review a few production records. Jesse believes that GMPs are...

SETTINGS

Answer Choices: Randomized
Hide correct answer count: No
Timed Bonus: No

AUTHORS

Missing Author

CREATED

Peter Murphy
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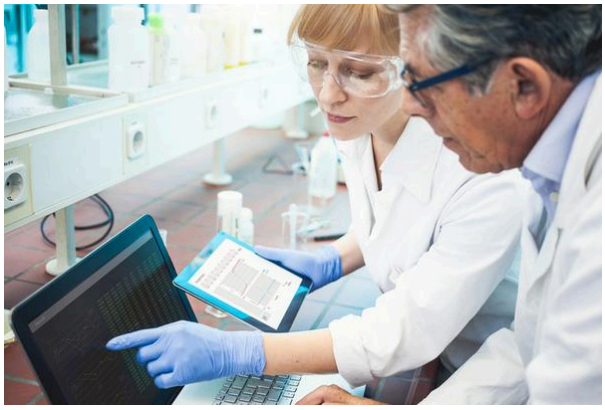
UPDATED

Peter Murphy
November 17th, 2023 @ 12:28 PM

TOPICS

GMP - What is GMP?



NO IMAGE DESCRIPTION

Sarah is talking with her colleague, Jesse, about Good Manufacturing Practices (GMPs) as they revie records. Jesse believes that GMPs are used only by drug manufacturing companies like theirs.

Sarah shares that GMPs also apply to companies that work with other types of products, includ

SELECT 3 ANSWERS

- ✓ Some foods
- ✓ Medical devices
- ✓ Blood
- ✗ Alcohol and distilled spiri

Answer explanation

NO IMAGE DESCRIPTION

Sarah knows that Good Manufacturing Practices (GMPs) are part of a system for ensuring consisten and quality of products. They are a set of federal regulations that have the rule of law and apply to:

- Manufacturers, processors, and packagers of drugs
- Medical devices
- Some foods
- Blood

LEARN MORE:

Get a quick overview of GMPs by reading this 1-minute article, *What is GMP?*

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