UNDERSTANDING ISO

SILAS INSKEEP

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What makes ISO important and how to play your part

by Silas Inskeep

The medical industry abides by standards set by the International Organization for Standardization. These are in place to maintain assurance of the quality and safety of products. In the event of federal oversight, we will fall under ISO 13485. This standard encompasses design, development, production, as well as storage and distribution. Everything we do will follow this standard.

GTI Rock Island is the first legal grow facility in the state of Illinois. We are the first facility to utilize a second shift. We have the opportunity to make history again and become the first facility to be ISO certified through commencing these practices now. Proper practices give us an advantage in the market, as well as forwarding our ability to grow. Most importantly we produce products that get consumed; it is as simple as that.

Charles Amadin, the General Manager at GTI Rock Island, is developing this vision through the compliance team. It is up to us to diligently follow through in practicing proper manufacturing practices.

ISO 13485 was first published in 1996 and is considered compliant with European regulatory standards as well.

Good manufacturing practices are enforced in the United States by the U.S. Food and Drug Administration

1

PPE

When entering the production floor one must be attired with a lab coat, hair net, facial hair covering, and have washed our hands thoroughly, immediately before walking beyond the break room doors.

In some areas, additional PPE such as gloves and eye coverings maybe required.

Employees keep our shoes on site, however, visitors must wear shoe coverings to shoe coverings as well.

2

SANITIZE

Work areas are an important aspect of ISO practices. Any surface that plant material will come in contact with must be sterile.

Beyond this, keeping product separate to ensure no cross contamination occurs is vital.

With any fear of being sick, it is necessary to take proper precautions. Remember sanitary practices and additional PPE to prevent spreading of bacteria.

3

GOOD HABITS

A glove is as sterile as what is has touched. Be sure to change gloves between plants and with any form of contamina10 tion.

Always properly remove and dispose of gloves between use.

Personal items must not come in contact with product.

"Good manufacturing practices are recommended with the goal of safeguarding the health of consumers and patients as well as producing quality products."

Q&A: MARK KIMBLE

Mark heads the compliance team and was nice enough to answer a few questions

WHAT IS THE MOST IMPORTANT THING TO KNOW ABOUT ISO?

It is important for our company to implement ISO 13485 so that we can plan, develop, and deliver goods and services that satisfy customer quality requirements.

WHAT DOES A DAY ON THE COMPLIANCE TEAM LOOK LIKE?

A typical day for the quality and compliance team consist of writing policies and procedures, internal compliance monitoring and auditing, enforcement of standards, and most important having an effective line of communication with all employees throughout the facility.

WHAT DOES THE ROAD TO CERTIFICATION LOOK LIKE?

Obtaining an ISO 13485 certification will require a team effort from everyone at the GTI Rock Island. The road to obtaining an ISO 13485 certification will be a challenging and will be the first in the national for the cannabis industry. We have put together a great team here at Rock Island to achieve this goal!

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BRIEF OVERVIEW OF ISO REQUIREMENTS

- Sustain a sanitary and tidy production area.
- Maintain controlled conditions to prevent cross-contamination and would be adulterants or allergens that could make our product unsafe for human consumption.
- Any changes to the manufacturing process need to be assessed to ensure there is no resulting change to the product.
- Instructions and procedures should be clear, understandable, and accessible to everyone. These ensure our processes are repeatable and there is no deviation of quality. Any departure from a procedure is expected to be investigated and documented.
- Records are to be maintained throughout the manufacturing and distribution process to ensure there is an accessible history. Staff should be able to look back and see every process the product went through.
- Records of manufacture and distribution enable a complete history of a batch in an understandable and accessible form. If a contaminated product made it into the hands of a consumer, documentation allows for measures to be taken to prevent the same circumstances occurring again.