

Together for your sustainable success



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# MEDICINAL CANNABIS -

Mission is possible, with GMP knowledge!





## WHY IS GMP FOR MEDICINAL CANNABIS NECESSARRY?

## production type

application of the guideline to steps of the respective production type

Source disclosures: EudraLex - Regulations for medicines in the EU Volume 4, GMP - Human and Veterinary Medical Products -Part II: Basic requirements for active substances for use as starting materials

If you want to get medicinal cannabis as a finished product, you need GMP in addition to GACP. This is a mandatory requirement!

## WHICH PRODUCTION STEPS HAVE TO BE CONSIDERED?



### Breeding and cultivation

» growing and selection of genetics



### Analytics

- » bioavailability
- » monograph

## Machinery and harvesting technology





### Plant engineering, with drying process

- » facility management, (e.g. temperature, light, humidity)
- » safety concept
- » drying methods

- » measuring technologys

- » processes validated, GMP complient
- » data management



#### Final release

- » final product development
- » measurements defined
- » neccessary documents defined

## MY ADDED VALUE FOR YOUR TARGETS!

- » GAP-Analysis; current status versus GMP regulations
- » Feasibility studies, e.g. appropriate production site, equipment
- » GMP expert, know how over 25 years (German regulations, FDA, Anvisa, etc.)
- » Well experienced in phytopharmaka
- » Project management/lead, e.g. creating concepts for production sites and implementation
- » Define and develop processes for production under GMP
- » Organizational Change Management on the shop floor and Management
- » Huge experiences in production and scale up
- » Increasing efficiency and optimizing the process organization
- » Interim Management as General Manager, Site Head or similar

## MY REFERENCES

In the last 20 years, I have gained a lot of experience and developed into a GMP expert in the production environment.

Well-known companies on this way:

- » Boehringer Ingelheim
- » Bausch & Lomb
- » Cesra Arzneimittel

