

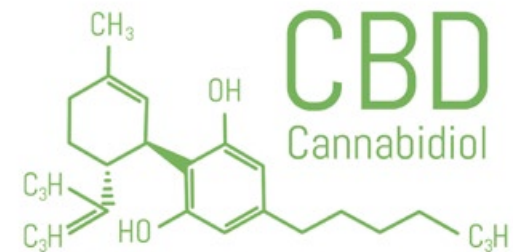


Marc Overesch

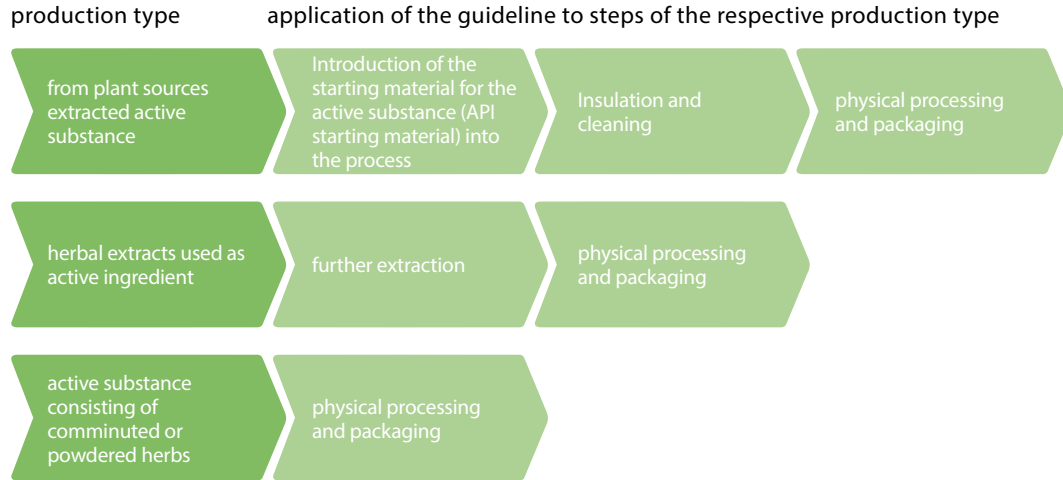
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MEDICINAL CANNABIS – Mission is possible, with GMP knowledge!



WHY IS GMP FOR MEDICINAL CANNABIS NECESSARY?



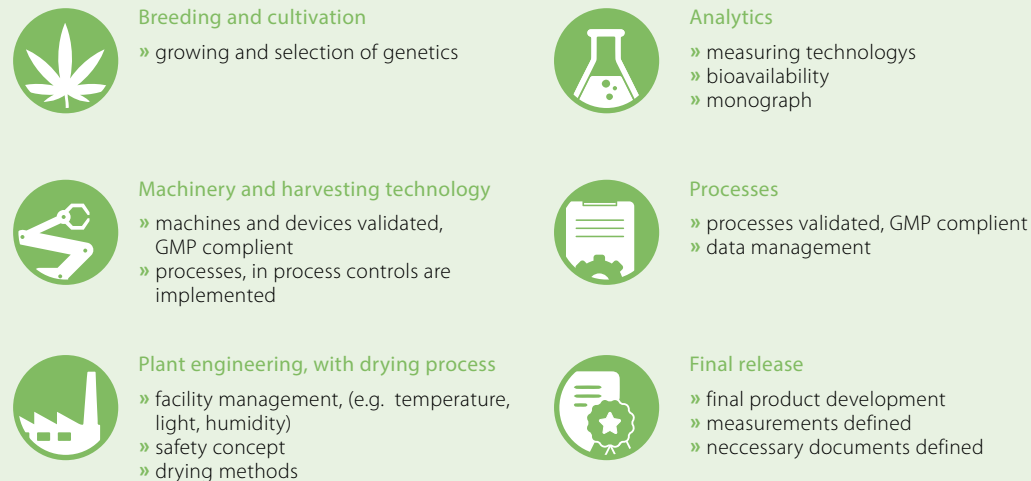
Source disclosures: EudraLex – Regulations for medicines in the EU Volume 4, GMP – Human and Veterinary Medical Products – Part II: Basic requirements for active substances for use as starting materials

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

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

WHICH PRODUCTION STEPS HAVE TO BE CONSIDERED?



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
- » B. Braun
- » Merz Pharma
- » Cesra Arzneimittel

