



International Conference on Cannabis and medicinal research during November 15-16, 2018 at Osaka, Japan.

Main theme of the conference is "Challenges and Barriers in Agronomy, Medicinal & upshot of Cannabis". <https://cannabisconference.blogspot.com/>

## Cannabis facilities risk management and compliance challenges between cGMP requirements & safety design issues. Case study: cGMP Cleanrooms classified space.

### Abstract

Risks management represent a major tool and an essential step in the process validation implementation during all the life cycle of cannabis manufacturing facility processes, from cannabis plant harvest and growth, THC & CBD oils extraction by means of supercritical CO2 technologies, till manufacturing of pharmaceutical, nutraceutical, cosmetics, as well as foods final products forms.

Risk analysis and management would be involved also to decide when and how cGMP design of manufacturing equipment, systems, processes, layouts and of cleanrooms shall be implemented.

Therefore, risks management and mitigation tools and alternatives are very critical to reduce volatile organic compounds (VOC), odours, chemical and biological hazardous and flammable and explosive processes issues, mechanical and design risks and related capital costs as well.

Cannabis plant growth and yields are very sensitive to watering processes monitoring, chemical and biological quality of related water, critical environmental parameters (CEP), heating, ventilation and air conditioning (HVAC) technologies, and related CEP control and standard operation procedures (SOP) implementation, bio-decontamination of air supply, air return and exhaust, of cannabis plant and watering, as well as of cannabis plant storage and warehouse. Therefore, risk analysis again is a powerful approach to target PURS and performance results.

### 8PURS (User Requirement Specifications) x 100



Risk management will drive also the choice of reasoned approaches for the proper management of the change controls (maintenance, metrology, ...), to reduce operations cost.

In this article, examples are given to show how is powerful approach Commissioning and Qualification (C&Q) based on risk management and mitigation. Furthermore, risk management approach is quite justified in particular when it comes to deal with complex processes involving multi-products facilities, highly potent products, flammable solvents (alcohol, acetone, ...) or explosive carbohydrates raw materials (ATEX, NFPA) as well as biological compounds containment.

Aziz Chraïbi, PhD, PEng.

**GMP** Engineering & Compliance Director

**CANNABIS, HEALTH CANADA & MAPAQ EXPERT**

CPMT Training Company Agreement #0059104

C.+1. 514-616-2692 | O.+1.450-600-0790 x 253 | <https://pbe-expert.com/en/sectors/cannabis-en/> | [goo.gl/aFnRSL](https://goo.gl/aFnRSL) | <http://goo.gl/HjanAr>

**PBE Expert in CANNABIS Process Building Engineering, GMP Cleanrooms, HVAC, Supercritical CO2 Extraction & Validation**

**We Process, Build, Engineer**



PBE, Pharma Bio Expert Inc.  
3210, rue Francis Hughes,  
LAVAL, Qc, H7L 5A7, Canada  
Tel: +1 (450) 600-0790