A GLOSSARY OF CANNABIS NOMENCLATURE

A Glossary of Cannabis Nomenclature

The word *nomenclature* is a Latin word which can be further dissected into two more Latin words *nomen* ('name') and *calore* ('to call'). The word *nomenclature* refers to a list of names, as does the word *nomenclator*, which can also indicate a provider or announcer of names. Put simply, nomenclature is the system of names and terms used in a particular industry or field of study.

Nomenclature is of critical importance to the rapidly developing global cannabis industry. The first step to learning anything new is to first understand the language. How can we ever provide effective training to industry stakeholders and regulatory officials without a common language to work from? How can we effectively compare products and regulations without agreement on what the terms within mean? Ensuring we are all using the same nomenclature drives effective communication, collaboration, and ultimately adaptive regulations. Other benefits of establishing a common nomenclature or vocabulary, include:

- Allows for the organization and classification of information in a systemized manor
- Permits people throughout the world to communicate about cannabis unambiguously
- Eradicates confusion in contracting
- Provides clarity and precision on global trade requirements
- Streamlines understanding of key business concepts
- Advances global trade

One extremely common phrase that exemplifies the importance of nomenclature to the cannabis industry is 'medical cannabis'

- In the US, this term typically refers to cannabis grown in a state that has legalized the production of cannabis for medical use. The term does not have any correlation to the type of cannabis grown, the way it was grown, the level of cannabinoids within the plant, or the quality of the product.
- In Europe, South America, South Africa, Australia, etc., medical cannabis is used to describe the cannabis species hemp that is grown for medicinal purposes.

Having a cannabis nomenclature system in place facilitates operations, regulations, and the progress of the industry overall by standardizing terms that enable communication despite linguistic and other barriers. The cannabis industry can learn a lot from the supplement industry, who proceeded without an agreed upon nomenclature, and as a result lost out on years of opportunities.

The purpose of this glossary is to provide a compilation of common terms and concepts related to cannabis, cannabis products, and the cannabis industry. Please note that this glossary does not include every term related to cannabis, but is the glossary used by the Foundation Of Cannabis Unified Standards (FOCUS).

While the glossary strives to provide the most common terms within the cannabis industry, less common terms can be found through the cited references.

FOCUS will continue to update this glossary regularly, and welcomes suggestions for changes and additions at GAP@focusstandards.org.

A

accreditation
Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. These tasks include sampling and testing, inspection, certification, and registration.

Active Pharmaceutical Ingredient (API)
Any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure of any function of the body of man or animals. The term includes those components that may undergo chemical change in the manufacture of drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

actual yield
The quantity that is produced at any appropriate phase of manufacturing, processing, or packaging of a drug product.

Adverse Event (AE)
The development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a cannabis product, whether causally related to the product.

aeroponics
A method of growing cannabis suspended in the air.

agitation
Harvesting trichomes from cannabis flowers through physical contact. Agitation typically takes place after freezing the product, to make the process more effective.

agricultural Inputs
Any material, compound, substance, or formula added to the cultivation process to control pests and disease, promote healthy growth or improve the harvested product to meet cultivation goals. Agricultural inputs include fertilizers, pesticides, and plant protection products.

air classifications
Classification of processing rooms or areas based on the allowed number of particles per cubic foot of air (USA) e.g. class 100, or particles per cubic meter (EU) depending on the level of activity in the processing room. The EU refers to these air classifications as Grade A through D, with A being the cleanest during normal activity.

airlock
An enclosed space with two or more doors, and which is interposed between two or more rooms, e.g. of differing class of cleanliness, for the purpose of controlling the air flow between those rooms when they need to be entered. Air locks are designed for and used by either people or goods.

alert levels
Established static and operational microbial or particulate levels giving early warning of potential drift from normal operating conditions which are not necessarily grounds for definitive corrective action, but which require follow up investigation.

alert limit
Established criteria giving early warning of potential drift from normal conditions which are not necessarily grounds for definitive corrective action, but which require follow-up investigation.

API starting material
A raw material, intermediate, or API that is used in the production of the API. An API starting material can be an article of commerce, materials purchased from one of more suppliers under contract of commercial agreements or produced in-house.

as found
The condition or status of equipment, instrumentation or systems prior to calibration or maintenance activities.

attestation
Issue of a statement, based on a decision following review, that fulfillment of specified requirements has been demonstrated.

audit
A routine inspection performed by either internal employees or an external third-party auditor. The goal of an audit is to determine if the cannabis company is meeting standards and regulatory requirements.

audit criteria
A list of expectations the cannabis company must meet to pass an audit.

B

batch
A defined quantity of cannabis or other material that is intended to have uniform character and quality, within specified limits, and is produced during the same cycle.

batch number
A group of letters, numbers, or symbols, or any combination thereof, from which the history of the manufacturing, packaging, labeling, or holding of a product or derived product can be determined.

batch production record
The document used for each individual batch, based on the master production instruction.

bioactive
Influencing a living organism, tissue, or cell.

biological agents
Microorganisms, including genetically engineered microorganisms, cell cultures and endoparasites, whether pathogenic or not.

biological contamination
Contamination by bacteria, yeasts, molds, viruses, or any other microorganisms that may be present.

biosecurity
Preventative measures designed to protect crops and property from the entry and spread of pests and diseases.

bio burden
The number of microorganisms that an object is contaminated with.

bulk product
Any product which has completed all processing stages up to, but not including, final packaging.

C

calibration
Comparison of a measurement standard or instrument of known accuracy with another standard or instrument to detect, correlate, report, or eliminate by adjustment any variation in the accuracy of the item being compared with the standard traceable to a recognized national standard.

cannabinoid(s)
A class of chemical compounds produced by the cannabis plant that act on the body's cannabinoid receptors.

cannabis
A genus of flowering plants within the Cannabaceae family identified by their distinctive glandular trichomes, divided serrated leaves and tough bast fibers.

cannabis-infused product
A topical, inhalable, or ingestible product that contains active cannabis or cannabis concentrate as a regular ingredient incorporated through homogenization or topical application.

cannabis oil
Concentrated liquid extracts from the cannabis plant.

centrifugation
A method of separating a solid/liquid mixture by rotating it at high speed in a cylindrical container. The solid will remain on the sides (through centrifugal force) while the liquid goes to drain.

Certificate of Analysis (CoA)
Document describing the quality and purity data from quality control testing of a lot or batch.

certification
Procedure by which a third-party give written assurance that a product, process, service, or person conforms to specified requirements.

Clean-In-Place
An automated cleaning process that relies on both chemical removal and physical agitation.

cleaning
Physical removal of dirt, debris, and other potential contaminants to the extent necessary for further processing or intended use.

cleaning validation
Proves that the documented cleaning procedure will consistently remove the previous product, or cleaning agent and reduce the microbial population to a safe and acceptable level.

clones
A cannabis plant clipping that is planted and grown to create a genetic copy of another plant.

close out meeting
The last formal meeting is held between the client and the auditor before the auditor leaves the facility.

closed loop extraction
A closed loop extraction system that recycles solvent or C02 in a closed system, instead of releasing it into the air.

cold storage
The storage of products requiring a specific storage temperature or required to be stored frozen.

colony forming unit (cfu)
A microbiological term that describes the formation of a single macroscopic colony after the introduction of one or more microorganisms to microbiological growth medium. One colony forming unit is expressed as 1 CFU.

compliance
Compliance is used to describe an organization that is meeting all regulatory requirements.

composition
The aggregate mixture which results from the manufacture of a product according to the formula and process defined in the product's manufacturing protocol.

component
A substance or item intended for use in the manufacture of a product including ingredients, additives, fillers, other ingredients, and processing aids.

complaint
A complaint is any expression of dissatisfaction with a marketed product or service.

components
Any ingredient intended for use in the manufacture of a cannabis product, including those that may not appear in such products.

concentrate
Any type of cannabis product that is refined from aboveground plant components into a more purified and potent form. A concentrate can refer to any form of hash, rosin, kief or forms of hash oil (shatter, wax).

conformity
When the output meets the requirements, and inversely, nonconformity is when the output fails to meet one or more requirements.

conformity assessment
Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.

conformity assessment procedures
Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled (e.g., testing, inspection, certification, accreditation).

contact surface
*A*ny boundary region that directly touches cannabis, components, or cannabis-derived product, and any boundary region from which drainage onto cannabis, components, or cannabis-derived product, or onto other regions that touch cannabis, components, or cannabis-derived product, which may occur during the normal course of operations.

contact time
A predetermined time that a test microorganism is exposed to the activity of a test material.

contaminants
Any biological or chemical agent, foreign matter or other substances not intentionally added to products that may compromise product quality, safety, or suitability. Any material that potentially has adverse impacts on the functioning of, and/or shows an undesirable interaction. Contaminants include insects or insect parts, feathers, fingernails, cosmetics, jewelry, hair, feces, mold, decomposition or visible growth, visible adulterants, lubricants, glass shards from glassware or lighting, metal shavings from equipment, staples, plastic, wood splinters, stones, sand and foreign plant parts.

contamination
The presence of any foreign substance in a product, be it physical (e.g. foreign objects), chemical (e.g. degradation of products) or microbial (e.g. bacteria).

continuous improvement
All business activities that are driven towards the constant improvement and betterment of their systems and processes.

continuous monitoring
Ongoing sampling of environmental conditions throughout the period of operations, ensuring that update of data constantly occurs.

controlled access area
*A*n area in the physical plant, dispensary, or location, designed to prevent entry by anyone except authorized personnel.

controlled environment
Any area in an aseptic process system for which airborne particulate and microorganism levels are controlled to specific levels that are appropriate to the activities conducted within that environment.

correction
Any repair, rework, or adjustment related to the disposition of an existing non-conformity, defect, or other undesirable situation.

corrective action
An action that needs to take place to improve processes. The action is taken to eliminate the causes of an existing non-conformity, defect, or other undesirable situation to prevent recurrence.

counterfeit product
A cannabis product that looks identical to an original product both in appearance and packaging but does not contain active ingredients or has been made illegally.

crisis management plan
Crisis management plans document procedures to prepare for, manage and recover from events that could interrupt business operations including natural disasters, fire, flood, chemical spill, loss of key staff, sabotage, vandalism, terrorism, theft, robbery, workplace violence, seizure of assets or property, product contamination and product recall.

critical complaint
A complaint that strongly indicates the purity, identity, safety, or efficacy of a product may have been compromised and has the potential to cause a life threatening or serious health situation.

critical control points
Designated points in a production process where failure to follow or meet a standard procedure or process step could cause harm to products, customers and the business; the operation documents each critical control point in the Hazard Control Plan along with the critical limits for each CCP.

critical deviation
Deviation from standards and/or regulations that provide immediate and significant risk to product quality, patient safety, or data integrity, or the combination and repetition of major deficiencies that indicate a critical system failure.

critical item
Items which have been assessed to impact product quality, safety or efficacy or otherwise present an unacceptable hazard if the equipment or its protective system should fail, and that failure or malfunction could lead to danger to life or significant harm to any person or environment.

critical limits
The maximum and/or minimum parameters allowed by each critical control point to ensure product quality. Critical limits are based on existing standards, scientific research, regulations, GMP, production data and results, and equivalent verifiable sources.

crop cycle
The time from initial planting to harvest of a discrete group of plants cultivated in the same area, using the same methods, and using the same agricultural inputs.

cultivar, cannabis
A plant variety that has been produced in cultivation by selective breeding.

cultivar, commercial
Cannabis that is grown for the purposes of fiber, textiles, biofuels, bio/phytoremediation, or any other purposes not intended for human and/or animal consumption.

cultivar, multi-purpose
Cannabis that is grown for multiple end uses whether that be for a combination of drug, nutritional and/or commercial purposes.

cultivar, nutritional
Cannabis that is grown for the purposes of seed production or any other purposes intended for human and/or animal consumption except for the purposes of collecting, isolating or extracting the essential oils, resins, saps, glandular trichomes, and flower(s).

cultivar, resin
Cannabis that is grown for the purposes of collecting, isolating, or extracting the essential oils, resins, saps, glandular trichomes, or flower(s) intended for human and/or animal use.

cultivate
*T*o grow, harvest, dry, and cure agricultural products.

cultivator
A person, group of persons, non-profit entity, or business entity that grows drug, nutritional, and/or commercial products.

***current good manufacturing practices* (cGMP)**
(cGMP) ensure that products are consistently produced according to quality standards. The term Good Production Practices (GPP) may also be used.

cure/curing
The process of slowly drying flowers of the cannabis plant to remove sufficient moisture from the plant to prepare it for processing or finishing, ensure shelf stability and minimize microbiological growth.

D

dead legs
An engineering term referring to a length of pipe, usually at right angles to the main pipe, that does not allow full flushing of the pipe to remove its contents. With a dead leg system residues or cleaning agents can remain in the "dead" area after cleaning is completed.

de facto standard
A de facto standard — or ad hoc standard — is based on common practices that are well-established. De facto standards for format, language, or protocol, have wide general acceptance although they are not formally recognized by a standards developer.
Common de facto standards include the arrangement of keys on a typewriter or keyboard (QWERTY keyboard) and the MS-DOS computer operating system.

declaration
First-party attestation.

decontamination
*T*he use of physical or chemical means to remove, inactivate or destroy microorganisms on a surface or item so there are no infectious organisms and the surface or item is rendered safe for handling, use or disposal.

design qualification
Documented verification that the proposed design of the facilities, equipment or systems is suitable for the intended purpose.

deviation
A departure from standard procedures or specification resulting in non-conforming material and/or processes, or where there have been unusual or unexplained events which have the potential to impact product quality, system integrity, or personal safety.

deviation report
A form used to monitor and record circumstances which do not meet acceptance criteria or GMP guidelines during validation.

disinfectant
A physical or chemical agent or process that destroys pathogenic or potentially pathogenic microorganisms on inanimate surfaces or objects. A disinfectant is not necessarily expected to kill spores or viruses. A disinfectant is not expected to necessarily achieve sterility.

dispense
To remove a specific quantity of cannabis or cannabis-derived product from the primary material and portion into a secondary container for release to compliant individuals and/or entities.

dispensing operation
A person, group of persons, non-profit entity, or business entity that provides cannabis or cannabis-derived products to individuals or other entities.

disposition
*R*eview and approval or rejection of a batch, lot, or other item by quality control personnel.

document control
Assuring only the most up to date documents are being used and referred to at any time.

drug
Articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)."

drug substance, botanical
A product intended for use in diagnosing, curing, mitigating, or treating disease that would meet the definition of a drug under section 201(g)(1)(B) of the FD&C Act and would be subject to regulation as such.

due diligence audit
Audits performed to evaluate if an external organization identified for in-licensing, acquisition, or collaboration is fit for purpose.

E

effectiveness
How well a plan or operation is functioning. Effectiveness is determined by how much unnecessary time is unnecessarily spent on tasks.

efficacy
*T*he proven performance of a product established under defined conditions *extract, n* - An article with liquid, solid, or semisolid consistency in which the constituents of interest are completely or partially separated from other components with the aid of water, alcohol, alcohol-water mixtures, or other suitable solvents.

endotoxin test
A test designed to determine if there are fever producing substances in the cannabis product. This substance can be produced by the degradation of gram-negative bacteria from their cell walls. Endotoxin is harmful to humans.

environmental monitoring program
A documented program which describes the routine particulate and microbiological monitoring of production and manufacturing areas that includes a corrective action plan when action levels are exceeded. This program provides meaningful information on the quality of the environment when a given batch is being produced or manufactured, as well as environmental trends of the area. Programs must identify potential routes of contamination, allowing for implementation of corrections before contamination occurs.

excipient
Substances other than the cannabis or cannabis ingredients (API) that are intentionally included in the product.

exit package
Packaging and labeling that encloses a final consumer product when it is sold or dispensed to a customer.

expiration date (expiry date)
Indicates the date after which the cannabis or cannabis product cannot be guaranteed for safe use. This can also be used to describe the date placed on the containers/labels of an API designating the time which the API is expected to remain within established shelf life specifications if stored under defined conditions, after which it should not be used.

extraction
Process or method for collecting, isolating, or removing any substance from a source material, whether bioactive or not. Extracting cannabis compounds into a concentrated substance using solvents such as water, ethanol or CO2, or physical separation such as sieving or friction to remove trichomes.

extract, inhalation
Extraction products that are explicitly produced for the purposes of being absorbed through the lungs with or without combustion or heating (aerosolized mist, smoke, sprays, vapors, or other methods).

extract, commercial
Extraction products that are not explicitly produced for the purposes of inhalation through combustion and/or vaporization.

F

feedback
Comments on products, services, and work environments from an end user, employee, supplier, or vendor.

finished goods
Cannabis materials or products that have undergone all stages or production, including packaging in final containers that are released for storage, delivery, sale, or use.

first in – first out
A manufacturing principle whereby the first stroke that arrives is the first stock picked for use.

first, second, and third party
Relates to the person or organization that performs the conformity assessment. First party is usually the manufacturer or supplier. Second party typically involves the patient or consumer, or other parties with an interest in the object undergoing conformity assessment. Third party is the person or body that is recognized by being completely independent of the parties involved, as it concerns the issue in question.

fertilizers
Substances that provide essential nutrients for plant growth, such as nitrogen, phosphorus, or potassium. Generally used to promote or enhance growth characteristics. Fertilizers may be derived from raw plant material, composts, and other organic matter.

fungus/fungi
Microorganisms with a separate nucleus contained within a cell wall. Molds and yeasts are typical examples of fungi.

fungal spore
*G*eneral term for a reproductive structure in fungi.

G

gang-printed
A label for one product that is printed simultaneously on the same sheet of paper as labels for other products.

Gap Analysis
An initial assessment of a cannabis company's operations, systems, and processes to determine what business requirements are currently being met, and what is required to bring the company closer to meeting requirements.

global standards
Standards that are universally accepted and used around the world independent of their source or standards development process.

Good Agricultural Practices (GAP)
A set of operational practices that verify agricultural products are produced, packed, handled, and stored as safely as possible to minimize risks of food safety hazards.

Good Distribution Practices (GDP)
Practices related to the transport and distribution of cannabis and cannabis products.

Good Laboratory Practices (GLP)
GLP principles provide a scientific and quality framework to plan, perform, monitor, record, report and archive laboratory studies and tests. ISO 17025 is the general benchmark for GLP.

Good Manufacturing Practices (GMP)
Good Manufacturing Practices ensure that products are consistently produced according to quality standards. The term Good Production Practices (GPP) may also be used.

H

hazard
A biological, chemical, or physical agent or condition with the intrinsic capacity to cause an unwanted or adverse effect.

hazard analysis and critical control points (HACCP)
HACCP is a detailed, systematic, documented approach that identifies, evaluates, and controls quality hazards for each product-related process used by an operation. HACCP may be applied to GAP or GMP requirements. FOCUS Standards use the terms Hazard Control Plan and HACCP Plan interchangeably.

health and safety program
A comprehensive health and safety program include physical safety, safely designed work processes, safe tools and equipment, facility and environmental safety, regular safety assessments, worker engagement and ongoing safety training.

hemp
The plant of the genus Cannabis or any part of the plant, containing low levels of delta-9-tetrahydrocannabinolic acid, which is used for fiber, seed, or processing of non-THC cannabinoids.

hempseed
Sterilized seed of nutritional cultivars of cannabis which are incapable of germination but are intended for human and/or animal consumption. The words "heart" and "nut" are synonymous with "seed".

holding
Manufacturing, processing, packing, or holding of cannabis and cannabis products includes packaging and labeling operations, testing, and quality control of cannabis products.

homogeneity
How evenly distributed the cannabis extract or API is distributed throughout a product. Homogeneity provides end users assurance that they are consuming a consistently distributed product.

housekeeping
Activities designed to keep a facility in a clean, sanitary, and well-maintained condition.

hypha/hyphae
Tubular filament of fungal cells; the basic vegetative structure of the body of fungi (excluding yeasts).

I

identity
The set of characteristics by which an ingredient or product is specifically recognizable or known.

implementation
The process of putting a system, plan, or standard into place.

improvement
Continually bettering your systems and processes to ensure the highest quality is provided.

inactive ingredient
Any component other than an active ingredient.

infrastructure
The operations of all departments that are run by a cannabis company. Infrastructure can include physical locations, as well as hardware and software owned by the business.

infused products
A food product, tincture or salve that contains concentrated or cannabis-derived cannabinoids.

ingredient
Any component that is added in the manufacture of a product.

injury and illness prevention plan
An ongoing intervention method to reduce the number and severity of workplace-related injuries and illnesses. Program components include management leadership, worker participation, hazard identification, hazard prevention and control, training, and evaluation of results.

in-process control
Checks performed during production to monitor, and, if necessary, to adjust the process to ensure that the product conforms to its specification. The control of the environment and equipment may also be considered part of in-process controls.

in-process material
And material that is compounded, blended, ground, extracted, sifted, sterilized, or prepared in any other way by the operation for use in manufacturing, packaging, or labeling.

inspection
Examination of a product design, product, process, or installation and determination of its conformity with specific requirements or, based on professional judgment, with general requirements.

investigation
A formal and documented review of a deviation, issue, incident, or problem to identify its root cause and determine the actions required to address it.

inventory
Inventory is the finished goods and materials that a cannabis business holds.

L

label
Written, printed or graphic information on or accompanying any article or any of its packaging, containers, or wrappers.

labeler
A person, group of persons, non-profit entity, or business entity that affixes information onto a package or product.

labeling operation
A facility where labeling occurs.

labeling
To affix information on packaged products.

lab management system (LMS)
Business, operational, quality and data processes and systems that ensure the lab operates according to policies and procedures.

limit of detection (LOD)
The lowest concentration of an analyte that can be reliably measured by a given testing method.

limit of quantification (LOQ)
The lowest possible concentration that can provide quantitative results by a given method.

line clearance
Cleaning the area and machines, removing all previous product and waste, and reconciling all material and product from the previous batch.

lot
A specific identified portion of a batch, that has uniform character and quality that is intended to meet specifications for identity, purity, strength, and composition.

lot number
Any distinctive combination of letters, numbers, or symbols from which the complete history of the production, manufacture, processing, packaging, holding, and distribution of a batch of cannabis or cannabis products can be determined.

M

maintenance
The combination of all technical, administrative, and managerial actions intended to retain it in or restore it to a state in which it can reliably perform a required function. Maintenance can be planned or unplanned.

management system
A management system is a process that organizations use to help set up and organize policies, objectives, and more. Management systems can be designed to control a variety of different conditions, including environmental, financial, quality, food safety, and occupational safety and health.

manufacture
*T*o compound, blend, grind, extract, or otherwise make or prepare cannabis or cannabis products. This includes all operations of purchasing of materials and products, production, quality control, release, storage, and distribution of cannabis products and the related controls.

manufacturer
A person, group of persons, non-profit entity, or business entity that holds a manufacturing licensing authorization to produce cannabis products.

manufacturing operation
A facility where cannabis products are made.

market acceptance
Includes the private sector standards and conformity assessment measures that retailers and consumers expect products to meet to be placed in a market. These measures sometimes differ from and exceed the applicable market access requirements.

market access
Includes governmental technical regulations and the conformity assessment measures that the government requires to demonstrate compliance with these technical regulations.

master equipment list
A master equipment list identifies each piece of equipment used in the production process including machinery, test systems, computing and measuring equipment, appliances, devices, vessels, wares, utensils, and tools.

master production record
The approved process, document, and recipe that is used for preparing every batch of the intermediate and final cannabis and cannabis products.

master sanitation schedule
A Master Sanitation Schedule identifies each area, piece of equipment and support item to be cleaned; the frequency of cleaning; and workers responsible for cleaning.

Material Safety Data Sheet (MSDS)
A document provided by a supplier indicating the proper safety procedures for handling or working with a particular substance.

medical cannabis
Cannabis and cannabinoid materials that are produced and used for medicinal purposes in accordance with applicable regulatory standards.

medical dispensary
A facility, operation or company licensed to dispense medical cannabis to qualified patients according to state and local laws.

method
A comprehensive description of all procedures used in a sample analysis.

microbial testing
A test used to determine the type and quantity of organisms in cannabis and cannabis products.

mislabeling
Occurs when labeling and packaging information does not accurately reflect the contents of the container. Mislabeling can be both intentional and unintentional.

monitoring
Checking processes to assure they are operating in compliance. Monitoring must be done on a continual basis.

must vs. should
The terms *must* and *shall* are used interchangeably to indicate requirements to the FOCUS Standard. The terms *should, could, may* and *can* are used where flexibility is permitted, or the standard is offering examples or guidance rather than directing specific requirements.

mycotoxin
A secondary metabolite of micro fungus that is capable of causing death or illness in humans and animals.

N

National Standards Body (NSB):
One public or private sector organization that serves as an economy's member body to the International Organization for Standardization (ISO). In addition, some NSBs may also serve as a coordinator of domestic standards activities.

negative pressure room
Pressurized room that keeps dust and contaminants within a room and prevents dust and contaminants from getting into other rooms.

non-conformance
The non-fulfillment of a specified requirement. A non-conformance usually leads to rejection or reworking of the item or process.

normal flora
Micro-organisms which normally inhabit a healthy human body or natural environment.

normal operating range
The normal operating limits of the instrument, equipment, or system as required for operation within a process.

O

objective
A goal set by a cannabis company that has execution planning behind it. Objectives include a series of actionable items to reach the goal, as well as possible obstacles that may be faced while attempting to meet the goal.

open ended questions
A question in which respondents are free to reply in their own words rather than being limited to choosing from among a set of alternatives. An open-ended question is usually followed by a probing question to clarify or amplify information.

organic load
The level of organic material (i.e., soil, nutrients, residues, plant material, viruses, fungi etc.) on an item or in an area.

Out of Specification (OOS)
A finished product or raw material test result that falls outside of approved, registered, or official specifications or acceptance criteria. A validated OOS should result in non-conforming products.

output
The result of a process that has been successfully completed. There are 4 general types of output: software, hardware, processed materials, and services.

outsource
Utilizing external organizations and contractors to accomplish specific tasks.

P

pH
A symbol for the degree of acidity or alkalinity.

packaging
Any material used in the packaging of cannabis and cannabis products. Packaging materials should be referred to as primary and secondary according to whether they are intended to come into direct contact with the product. Packaging does not include any shipping container or

outer materials used solely for the transport of cannabis goods in bulk quantity.

parameter
A quantity associated with a population.

particulate monitoring
Testing of the processing air for various sizes of viable and non-viable particles.

patient
A person registered and/or qualified by a state, municipality or agency and authorized to purchase or receive medical cannabis from an authorized provider.

performance
A measure of how well or poorly a particular subject is doing in an area. For example, how efficiently tasks are being completed based on the time, resources, and finances used.

personal protective equipment (PPE)
Personal Protective Equipment is worn to minimize exposure to hazards that cause workplace injuries and illnesses due to processes, environmental conditions, chemicals, radiation, mechanical irritants, airborne contaminants or other risks capable of causing injury or impairment to any part of the body through absorption, inhalation, sound or physical contact. Personal protective equipment may include gloves, safety glasses and shoes, earplugs or muffs, hard hats, respirators, coveralls, knee pads, vests, and full body suits.

pesticides
Any chemical or organic substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, fungus, disease, or weed. Fungicides and herbicides are included under the definition of pesticides, as are any substances or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and any nitrogen stabilizers or fertilizer additive that is not itself a source of nutrients.

planned deviation
A deviation or change to test methods, laboratory or manufacturing procedures that has been planned and approved as part of a temporary change.

plant protection products (PPP)
Non-pesticide agricultural inputs cultivators use to protect and maximize cultivation outputs. PPP may include fertilizers or growth regulators.

plant regulator or plant growth regulator
A substance that physiologically accelerates or retards the rate of growth or plant maturation or otherwise alters a plant's behaviors, or affects products derived from the plant. Plant regulators are generally considered Plant Protection Products (PPP).

positive room pressure
Pressure that excludes outside air from entering a facility.

potable water
Also known as drinking water. Water, that as a minimum, meets national standards for water intended for human consumption. USA, Europe, and Japan water standards meet or exceed WHO guidelines.

preventative action
Proactive actions taken to eliminate potential problems to prevent occurrence or reoccurrence.

Preventative Maintenance System (PMS)
A system that brings together people, equipment, and procedures, including scheduled maintenance plans, to ensure that operations are available in accordance with its specification.

probing question
A question used to clarify answers or discover more in-depth information. Typically, probing questions are specific and focused and asked in follow up to a general question.

procedures
Description of how certain processes are to be performed to achieve a desired result and documents how and when steps will be completed. This includes the operations to be carried out, the precautions to be taken, and the measures to be applied directly or indirectly.

processing
Manufacture, processing, packaging, or holding of cannabis and cannabis products including packaging and labeling operations, testing, and quality control.

product
What an organization is selling. Products can be both tangible and intangible.

product recall program
A product recall program defines the methods for removing or correcting products that violate laws, present a risk of injury or gross deception, or are otherwise defective. Recalls are voluntary but can be requested by regulatory agencies; mandated recalls are reserved for urgent situations or when a firm is not achieving recall responsibilities.
Recalls require the prime manufacturer (may include wholesalers, suppliers, distributors, and retailers) to analyze the hazard, notify the supply chain and issue product return procedures. Recall does not include market withdrawal or a stock recovery, which is accomplished through normal stock rotation practices, routine equipment adjustments and repairs, etc. Almost all recalls are conducted on a voluntary basis by the manufacturer.

purity tests
Tests to ensure an accurate statement of the content of impurities, heavy metals, pesticides, residual solvents content in a sample.

Q

qualification
Action of proving and documenting that any equipment or ancillary systems are professionally installed, work correctly and leads to the expected results. Qualification is part of validation however the individual qualification steps alone do not constitute process validations.

quality
Established specifications for identity, purity, strength, composition, packaging, labeling, manufacturing, and storage. Quality can also be represented by how much time and energy is being used to accomplish tasks, or how many requirements are met.

quality assurance (QA)
The part of quality management focused on providing confidence that quality requirements will be fulfilled. Quality assurance is designed to prevent mistakes and defects in manufactured products and avoid problems when delivering products and services.

quality control (QC)
QC is the part of GMP that is concerned with sampling, specifications, and testing. The activity or measuring product and process parameters for comparison with specific standards to assure they are within predetermined limits and therefore, the product is acceptable for use.

quality control personnel
A person, persons, or group, within or outside of a manufacturing, packaging, labeling, or holding operation, designated to be responsible for the operation's quality control operations.

quality control sample
A spiked sample used to monitor the performance of a bioanalytical method to assess the integrity and validity of the results of the unknown samples analyzed in an individual batch.

quality management
Refers to any activity that is being performed by an organization to maintain and improve quality. This can include the adoption of quality policies, quality assurance, quality planning, and more.

Quality Management System (QMS)
A quality management system is an organization's system which implements policies and objectives into processes to help improve quality. This includes all business and operational processes and systems implemented, including structures, policies, procedures, processes, systems, controls , records, and resources needed to ensure quality products and services.

quality objective
The plan established to ensure that quality results are achieved properly.

quality policy
A quality policy document shows the standards an organization has set for itself in terms of improving and maintaining quality. A quality policy revolves around quality management principles.

quality risk management
A systematic process for the assessment, control, communication, and review of risks to the quality of the cannabis and cannabis products across the product life cycle.

quarantine
Material or products physically isolated from production, marked and controlled until formally authorized for release. Materials segregated and withheld from use lots, batches, or other portions of components, packaging components, in-process materials, or products whose disposition must be determined by qualified personnel. Suitability for use must be determined by quality control personnel.

R

raw materials
A general term used to denote a substance in its natural, modified, or semi-processed state used as an input to a production process for subsequent modification or transformation into a finished good.

recall
A recall is a request to return cannabis or cannabis products after the discovery of safety issues or defects that might endanger the end user or put the seller at risk of legal action.

reconciliation
Reconciliation compares the amount of material going into a process with the amount coming out of a process.

record control
How a business organizes their documents and records to have them readily available for management and employees to access. This includes removing outdated records and replacing them with updated information. Record control is like *document control.*

regulatory requirement
A task or action that is required from the organization by the regulatory agency to maintain compliance.

rejected
Material, work-in-process or finished goods that do not meet product quality specifications. Rejected material is dispositioned as "rework" or "dispose."

relevant
What is important to a specific part of the process at a given time.

repeat deviation
A deviation that reoccurs after the identification of actions identified in a previous deviation. This would indicate that the root cause of the previous incident had not been correctly identified or that actions had not been taken in a timely manner to effectively address the root cause.

reprocessing
The reworking of all or part of a batch or product of an unacceptable quality so that its quality may be rendered acceptable by one or more additional operations.

reproducibility
The precision of the method or process under the same operating conditions over a brief period of time. The variation because of differing operators using the same equipment. This often signals a need for improved training and more consistent procedures.

requirement
A task or action that is required from the organization to meet the requirements within a standard. Can be related to products, services, regulations, quality, etc.

resample
To take additional samples from the same lot of material previously tested.

residue testing
A validated analytical procedure that detects, identifies, and measures the presence of chemical substances, their metabolites or degradation products in or on raw or processed agricultural products.

responsibility
A task or role assigned to an individual or department that consists of what they are accountable for.

retail
A facility, operation or company licensed to sell cannabis to qualified adults according to state and local laws.

retest
Performing additional testing on the original sample where possible, or a new original sample according to an investigative plan when no determinant error is identified.

return
The sending back of cannabis or cannabis products which may or may not present a quality defect.

rework
Taking already manufactured cannabis materials and performing additional steps that are not part of the normal process.

revalidation
Routine activities taken to confirm that critical systems, equipment, and processes continue to operate in a validated state and in conformance with GMP.

review
An overview of how a process or situation went. Reviews typically come after an assessment and can be both internal and external.

risk
Calculating the difference in negative and positive features of a process, service, or operation. By assessing risk, organizations can determine exactly how much there is to gain from changing an aspect of a system or process.

risk assessment
An assessment of the potential risks associated with a cannabis company and its effects on both customers and employees. Typically risk assessments are based on both safety and business components.

root cause
The basic cause of a deviation, from which effective actions can be defined to prevent reoccurrence.

route of administration
The process in which cannabis or cannabis products enter the human body, travel into organs and tissues, and is metabolized into the body before elimination. The route of administration determines the effects of cannabis and cannabis products, as well as their absorption levels and time to affect.

run chart
Run charts are used to monitor manufacturing processes. A run chart specifies the target fill, lower and upper specification limits, and the actual amounts dispensed over time.

S

safeguard
A possible solution or preemptive action to prevent possible problems and reduce risks.

Safety Data Sheets (SDS)
A standardized form that contains detailed information about possible health and safety hazards of a product and how to safely use, store, transport, handle and dispose of a product. Under the Federal Hazardous Substances Act, suppliers must provide SDSs for all hazardous material as a condition of sale, and employers must make them available to workers in multiple formats for review.

sanitation
The reduction in microbial load (or bio burden) by chemical means. The reduction of contamination, usually achieved through cleaning as a preparation step, followed using chemicals, biocides, and disinfectants as sanitizing agents. **Sanitation does not guarantee the complete absence of microorganisms.

Schedule 1 (US)
Drugs, substances, or chemicals that currently have no accepted medical use and have a high potential for abuse. The schedule of a drug is determined by the US Drug Enforcement Agency (DEA).

second-party conformity assessment
Conformity Assessment that is performed or required by a person or organization that has a user interest in the object (e.g. the procurer, purchaser, or user).

scope
The area in which something is applicable or a radius for something to be effective.

security risk assessment
A security risk assessment reviews all threats (crime) and hazards (natural/man-made events) to assets (staff, public, product, currency, materials, and information) and is used to develop the operation's security program.

shelf life
Time period during which cannabis and cannabis products are expected to remain within the approved shelf life specifications, provided it is stored under the conditions defined on container label.

soil load
A chemical or physical material(s) included in a test procedure to simulate an organic load, conditions, or use.

solvent
An inorganic or organic liquid used as a vehicle for the preparation of solutions or suspensions in the manufacture of cannabis products.

specification
The detailed requirements which cannabis, cannabis products, and other incipient and ingredients used during manufacturing must conform. Failure to meet specifications results in non-conforming product, formal QA investigations, rejection of material or product, reprocessing, and typically corrective actions.

stability studies
Studies undertaken on primary and/or commitment batches according to a prescribed stability protocol to establish or confirm the shelf-life of cannabis or cannabis products.

standard
A document, established by consensus, that provides rules, guidelines, or characteristics for activities or their results" or "a document that provides, for common and repeated use, rules, guidelines or characteristics for products or related process and production methods, with which compliance is not mandatory."

Standards Developing Organizations (SDOs)
SDOs include professional societies, industry and trade associations and membership organizations that develop standards within their area of expertise. They may develop standards with their own members or in cooperation with other SDOs and interested parties. SDOs in the United States may choose to develop standards that are submitted to ANSI for approval as American National Standards (ANS). They may also develop standards outside the ANSI accreditation and approval process.

standard deviation
Observations of a less serious or isolated nature that are not deemed Critical or Major but require correction, or suggestions given on how to improve systems or procedures that may be compliant but would benefit from improvement.

sterility
Sterility is the absence of living organisms or the total removal of living organisms, usually by heat or chemical means.

strain
Plant varieties (cultivars) selectively bred to produce distinct, desirable traits and effects of Cannabis sativa. The traits and effects include differentiated products or can be cultivation traits such as fast flowering, pest resistance or high yield. There is no standard for cannabis strain naming and cultivators have cultivated and named hundreds of cannabis strains.

strategy
How a person or an organization plans to reach a goal successfully.

storage condition tolerances
The acceptable variation in temperature and relative humidity of storage facilities for different activities.

supplier
A general term used to cover both vendors and contractors supplying cannabis, cannabis products, ingredients, raw materials, packaging components, formulated products, or providing services to cannabis businesses.

Suppliers' Declaration of Conformity (SDoC)
Procedure by which a first party or supplier conveys assurance that the object of conformity fulfills specified requirements.

surveillance
Systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.

system
How a certain set of processes operates to work towards an objective.

T

terpene
Fragrant oils secreted from the resin glands of flowers that bind to different receptors in the brain to provide different effects. Terpenes can be found in other plants as well, not just cannabis.

testing
Determination of one or more characteristics of an object of conformity assessment, according to a specified technical procedure (test method). Action of carrying out one or more tests.

theoretical yield
The quantity that would be produced during any phase of manufacturing, processing, or packaging of cannabis, or cannabis products, based on the quantity of the components used, in the absence of any loss or error in actual production.

third-party conformity assessment
Conformity Assessment that is performed by a person or body that is independent of the person or organization that provides the object, and of user interests in that object.

tincture
A tincture is a liquid form of cannabis, typically made from glycerin or alcohol. Most tinctures are distributed through an eye dropper under the tongue for faster absorption.

topical
Cannabis products such as lotions, balms, and creams that are applied to the outside of the body and absorbed through the skin.

training plan
A plan established by a company for its employees and managers starting what training (both regulatory and job skills training) is required for the employee to be considered competent in the job.

traceability
Ability to trace the inputs, history, application, or location of that which is under consideration.

trichome
Trichomes are the crystalized glands that produce resin on cannabis flowers and leaves that contain different cannabinoids.

U

unidirectional flow
Airflow moving in a single direction, in a robust and uniform manner, and at sufficient speed to sweep particles away from the critical processing area.

unplanned deviation
A deviation or change to test methods, laboratory or manufacturing procedures that was unplanned and was the result of an incident or an error.

V

validation
The act of proving, in accordance with GMP, that any procedure, process, equipment, material, activity or system leads to expected results.

vendor
A vendor supplies articles of commerce for purchase by other companies. A vendor can provide cannabis or cannabis-derived products, ingredients, excipients, APIs, terpenes, or other materials or equipment.

W

warning letter
A letter sent by the Food and Drug Administration or other regulatory body to a company indicating that GMP violations were found. The expectation is that the company will respond with a designated time for an acceptable corrective action plan.

water activity (aw)
A measure of the free moisture in a component or product; it is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

water use plan
A Water Use Plan documents an operation's plans and procedures for water sourcing, storage, use, discharge, and testing. It defines the frequency for water testing and analysis and procedures to ensure tests are conducted as scheduled and incorporates local water regulations.

work-in-process
Material dispersed from inventory and released into the manufacturing process that has not been fully processed into a finished good.

worst case
Conditions within normal parameters most likely to cause failure.

Y

yield, actual
The quantity of acceptable material or product that is output at an intermediate or final stage of production or manufacturing.

yield, expected
The quantity of material or the percentage of theoretical yield anticipated at any phase of production or manufacturing based on previous data.

yield, theoretical
The quantity of cannabis that would be produced at any phase of production and manufacturing based on the quantity of material used, in the absence of any loss or error in actual production.

References and Additional Sources of Information

American National Standards Institute (ANSI) *Definitions for Conformity Assessment*

American Society of Testing and Materials (ASTM) *D37 Cannabis Terminology*

Food and Drug Administration (2017) *FDA and Marijuana: Questions and Answers*

Foundation of Cannabis Unified Standards (FOCUS*)* (2016) *Standards for the Primary Production/Cultivation, Manufacturing/Processing, Retail/Dispensary, and Testing of Cannabis and Cannabis Products*

ISO 9000 (2015) *Terminology: Glossary guidance on selected words used in the ISO 9000 family of standards*

ISO 9001 (2015) *ISO 9001: Terms and Definitions*

ISO/IEC 17000 (2020) *General Principals*

National Environmental Health Association (NEHA) *Cannabis 101: Glossary of Related Terms*

US Code of Federal Regulations: *21 CFR 110, 111, 117, 210, 211*

US Drug Enforcement Agency (2011) *US Conformity Assessment Principles*