Cannabis Analysis Lab Optimization Process

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Q: So, you've acquired your license from a state government for your cannabis testing laboratory, what's next?

A: We know from 12 years of experience just how challenging acquiring a license can be. The next steps involve 1.) maintaining that license and 2.) optimizing the efficiency of your existing lab operation. Optimizing a laboratory operation financially is mostly a process of examining lab procedures and changing them so they can produce more revenue for less cost, similar to principles of Lean Six Sigma Management. We've outlined the key factors below:

Revenue

Samples analyzed with *defensible* data
- More defensible sample matrix system
  - Why: less avoidable labor-intensive steps
- More repeatable extraction efficiency
  - Why: more accurate data with less labor
- Less interferences (pyrolysis, Maillard)
  - Why: more accurate data with less labor
- More accurate published COAs
  - Why: more consumer confidence in published results

Expenses

Cost of consumables
- Solvent use (sample prep & HPLC)
- Standard sourcing and use
- Filters
- Vials
- Clean-up reagents

Instrument Run Time (Throughput)
- Per-Sample Run Time
- Instrument Maintenance Schedule
- LQC Samples and QAQC
- Compliance
- Calibration Technique

Lab Staff Labor Costs
- Procedural efficiency v. sample load
- Unifying sample prep for multiple analyses
- Reducing labor-heavy and error-prone elements of lab SOP with more efficient and more defensible procedural strategies.
- Simplifying QMS compliance systems so they take less man-hours and are less error-prone

Q: So, what can we help you to optimize?

A: The most critical question is, what exactly can we help you get done that will help your growing business?

Unifying cannabinoid and terpene sample prep

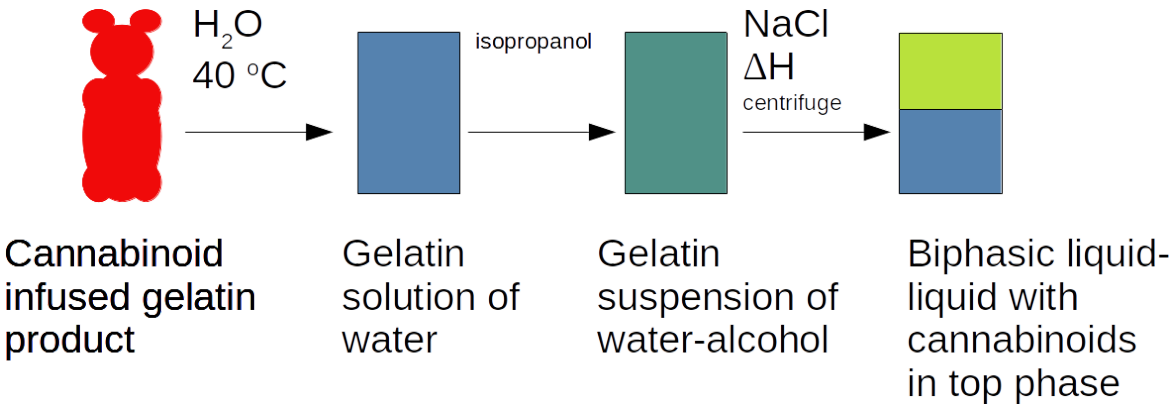
Many labs have two separate sample prep procedures that can easily be unified to reduce physical material and labor costs while producing the same data of the same quality. The most common is the sample prep for cannabinoids and terpenes in a cannabis analysis lab, which can easily be unified into a single sample prep with two sample extracts going to their respective instruments, producing fully defensible data with all associated LQC.

Cross-validating pesticides across LC and GC instrumentation

Many labs use two instruments for pesticide analysis but do not optimize their instrumentation for the most defensible data possible. Because many pesticides are accurate and defensible when analyzed on both LC and GC instrumentation. This means labs have invested in the capital equipment of instrumentation for defensibility on reported pesticide analytes that are basically being unused by the lab for want of method development, validation, and QMS defensibility. Digamma can help recuperate these resources and use them to increase both defensibility and throughput for a laboratory.

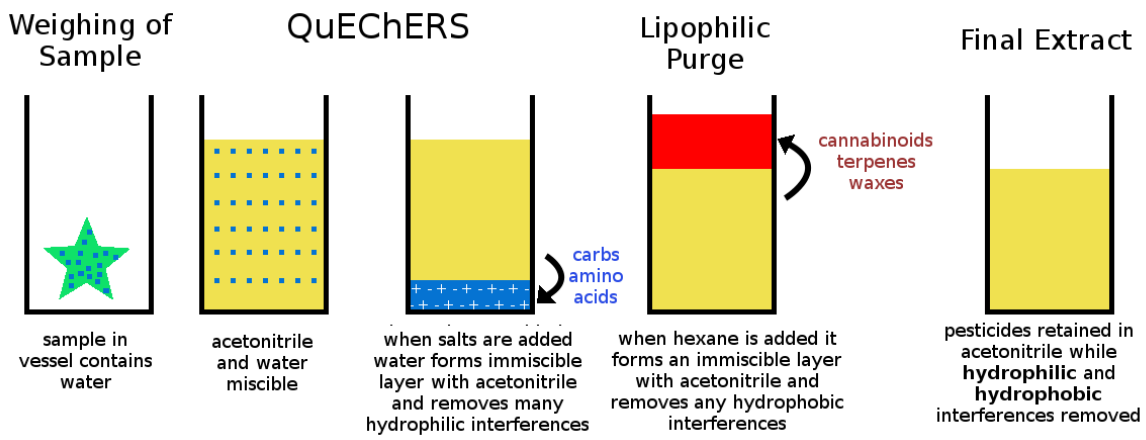
Cannabinoid High-Efficiency Extraction (Gummies, chocolate)

Many labs are extending the “dilute-and-shoot” sample prep approach that is appropriate for cannabinoids from cannabis flower in alcohol (usually methanol) to other matrix types and getting inconsistent results and wasting many man-hours in the laboratory repeating procedures. With simple concepts of chemical dis-incorporation and bi-phasic separation, Digamma has validated in many US states sample prep that is consistent, accurate, and inexpensive from a material cost, labor costs, and data management perspective. Using thermal concepts chocolates, skin creams, and many other hydrophobic matrices can be easily included in this optimization as well.



Pesticides Sample Prep (Sample Clean-Up)

Whether or not your lab has elected to use deutrated internal standards (^{2}H-IS) Digamma can help you optimize your pesticide method beyond the needs of state regulators for your initial validation. Having spent years optimizing the sample clean up procedures for pesticides in cannabis, we can help any lab transition from an initial “dilute-and-shoot” pesticide method into a legally defensible, efficiency, and repeatable method that will stand up in court, let alone regulatory audits. This involves years of knowledge in solvent chemistry, clean-up chemistry, and advanced ultra-trace calibration technique that allows our labs to know their pesticide results are accurate the first time, and every time they generate a result.

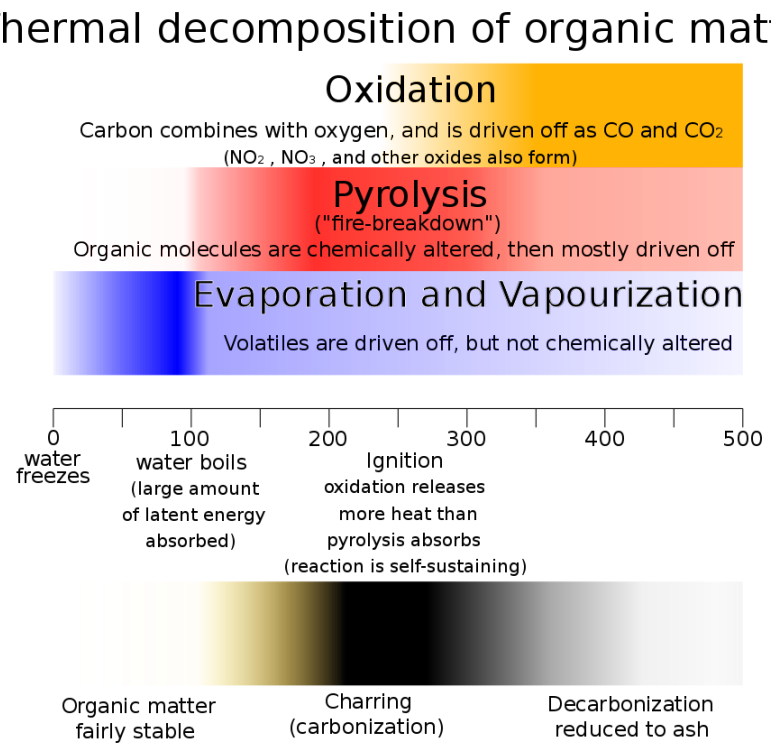


Unifying sample matrix type: 4 recommended, 3 possible

Many cannabis testing labs receive a wide variety of samples from a very diverse base of producers, and this creates issues for their laboratory procedures and internal and external compliance of a testing laboratory. Luckily, Digamma has seen all these sample types for many years and has a singular, efficient, and fully defensible system to process all sample types into 3 or 4 matrix class categories, all of which produce fully compliance LQC and QMS data for the lab’s compliance documents. This system involves 4 categories: A (flower), B (concentrate), C (hydrophilic) and D (hydrophobic) which encompasses all sample types submitted to modern cannabis testing laboratories. Some labs elect to unify samples C and D into a single category, and this is possible in certain analyses, particularly the most expensive (solvent, pesticide, heavy metal, and micro).

Residual solvent issues: evaporative loss, pyrolysis, oxidation

Many laboratories who have experience with analytical chemical processes that enter cannabis still have challenges with residual solvent analysis, particularly the head-space analysis aspect. There are multiple issues that relate to gas-phase sampling that are not relevant in liquid injection methods that are the analytical chemistry standard. These include evaporate loss, which we address with high pressure vial seals and sub-zero temperatures. These also include ultra-trace contamination from use of routine lab solvents (methanol, acetonitrile, isopropanol, etc), which we address with low-cost filtration systems. And finally the most irascible issue, the *in situ* generation of interfering products and even contaminant target analytes due to pyrolysis, Maillard product formation, and oxidation which we address with solvent extraction and temperature optimization procedures.



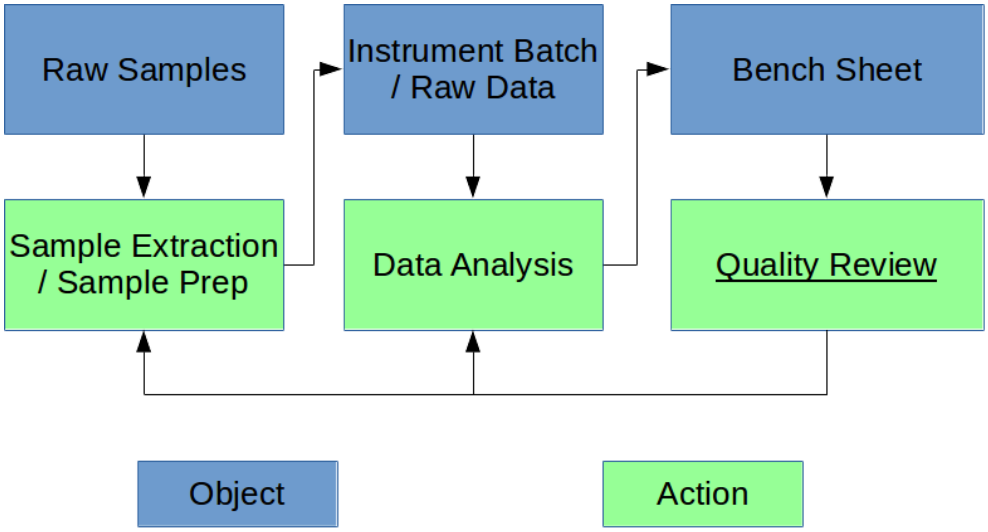
Reducing lab tech man-hours per sample processed

The biggest cost in any business is labor, but this age old axiom has become even more true in the era of computer and robotic automation, which is more directly applicable in the analysis laboratory than many other types of businesses. By reducing procedures to be both easier to perform and less error-prone, the number of expensive man-hours paid out by a lab will be reduced. But a secondary effect of this process is that the procedures that the lab staff will be performing will be more robust, meaning variation from one staff to another will be reduced, and the lab's dependency on a given staff member will be reduced as the procedure, intellectual property of the laboratory, takes the place of the chemist as the "star player" or "MVP" that keeps the lab procedures running. This concept is seen in many of the above states key issues but has a global impact that cannot be tied to any one analysis or procedure.

Simplifying data processing and QMS compliance procedures, increasing defensibility

Data defensibility represents the biggest risk to an existing analytical lab which already holds its license, and the biggest arsenal for this argument is in the QMS program the lab sets up to prove its defensibility and compliance with both specific regulations and standardized industry practices in analysis generally. By using either Digamma's pre-existing QMS system or using our insights to adapt your lab's existing system, we can make the work of proving the accuracy of your results routine, easy, and cheap. This service is ideal for ISO 17025, state

audits, or 3rd party proficiency such as Emerald's PT Reprot. The process has been defined quite well in federally regulated industries such as the EPA and FDA and is the basis of Digamma's cannabis analysis solutions. This allows for easy processing of QMS verification requests and the ease and cost efficiency of maintaining such a defensibility system for your laboratory. This also aligns your project well with the future federal legalization and regulation of cannabis as the FDA and EPA regulatory protocols on testing labs are the best indication of how the new and more profitable and stable federal market that cannabis is projected to expand into the US will affect your laboratory.



Screenshot of Sample Digamma Automated QMS Program:

	A	B	C	D	E	F	G	H	I	J	K
1	Batch Name										
2	Batch Date										
3	Batch Data File		Well Prefix→	BAC_QC_		Well Prefix→	FUN_QC_				
4				BAC_QC_	BAC_QC_	BAC_QC_	FUN_QC_	FUN_QC_	FUN_QC_	FUN_QC_	FUN_QC_
5			Batch	Bacteria			Fungi				
6	Batch LQC		All Targets	STEC	SAL	CANN	FLAV	FUM	NIG	TERR	CANN
7	PB	QC Prep Blank	PASS	PASS	PASS	-	PASS	PASS	PASS	PASS	-
8	PBM	QC Prep Blank Matrix	PASS	PASS	PASS	+	PASS	PASS	PASS	PASS	+
9	PC	QC Positive Control	FAIL	FAIL	FAIL	-	FAIL	FAIL	FAIL	FAIL	-
10	PCM	QC Positive Control Matrix	FAIL	FAIL	FAIL	-	FAIL	FAIL	FAIL	FAIL	-
11	REP	QC Replicate	FAIL	FAIL	FAIL	-	FAIL	FAIL	FAIL	FAIL	-
12											