SCOPE OF SERVICES

Manufacturing Facilities: Extraction and Formulation Laboratories

Note: This is just a scope of services document and not a proposal for a specific project. If you would like Digamma to generate a custom proposal for your project, please send a request to admin@digammaconsulting.com and someone will follow-up shortly.

This document is an outline of our proposal for an application for a cannabis manufacturing facility. Having discussed the needs for consultation for the client both for the application and planning process, and the implementation of facility operations if the application is accepted, we find it helpful at this stage to separate our proposed engagements with your business into an immediate smaller engagement geared towards the application process, with a follow-up to a longer and much more complicated engagement geared towards implementation of facility operations.

We have based our approximations of application material and therefore time and cost of the project from previous similar applications to state governments. We have summarized the estimates and approximate contents in Appendix A.

Appendix B outlines the main document that is used in running an extraction and formulation laboratory facility (sometimes called a “production” laboratory), which is the Facility Operations Plan and Quality Manual. Although the SOPs outline the day-to-day steps of the staff, the Operations Plan and Quality Manual outlines how the facility is managed, documented, and evaluated. As this would represent a large portion of the technical aspect of your client’s application to the state, it also represents one of the greater aspects of Digamma’s value to your client.

Appendix C has the list of the most popular cannabis-infused products made by manufacturers and the heat requirements of these procedures.

All appendices will be helpful in coordinating with the non-technical aspects of the application that need to be addressed that are outside the scope of Digamma’s technical expertise in laboratory processes. This will be important to coordinate with the rest of the team working on the application to prevent redundancies and, more critically gaps, in coverage of the application content.

Custom services such as optimization of extraction, concentration, distillation, or formulation steps with an eye to yields and material resource efficiency are difficult to quantify in pre-packaged services but are invaluable in reducing waste and loss in a manufacturing operation. This can be custom-generated based on the needs and specifics of the operation

needing to be optimized. Variables that are relevant to share with Digamma's team when generating a custom proposal are the scale of the process to be optimized, the relevant metrics of material resources such as starting and ending material, and the equipment and techniques used in the process.

A business's operational plan outlines the specific nature of the laboratory's extraction, production, and formulations. Finalizing these issues with a direct consultation with laboratory scientists with the experience to compare costs, risks, and complexity of the different options open to the client. Before proceeding through the facility-specific content, finalizing these aspects of the operational plan will provide robustness to the business plan and the license application.

If you have any other questions that we can answer, please don't hesitate to let us know.

Sincerely,

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CEO
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APPENDIX A

DIGAMMA LICENSE APPLICATION, CANNABIS MANUFACTURING FACILITY

We have summarized our dissection of technically focused laboratory processes of an application below. Because the application is a written document we have geared these tasks by estimated page numbers, which we have indicated with a column, for each aspect or mock document that would be submitted as part of the application. There are many non-technical aspects of the application that are not covered in this appendix.

Item	**Est. Pages**	**Man-Hours**
Operational Plan Consultation	–	3
Facility Blueprints and Plans		15
Facility Safety Plan	20	10
Facility Operations Plan and Quality Manual	50-300	40
Facility SOPs		
Facility SOP: Extraction	10	5
Facility SOP: Fromulation01	10	5
Facility SOP: Formulation02	10	5
Facility SOP: Formulation03	10	5
Facility SOP: Formulation04	10	5
Facility SOP: Formulation05	10	5
Facility SOP: Formulation06	10	5
Facility SOP: Formulation07	10	5
Facility SOP: Formulation08	10	5
Facility SOP: Formulation09	10	5
Facility SOP: Formulation10	10	5
Facility SOP: Analysis (Cann.)	20	5
Total	**200-450**	**128**

***Note:** that the bonus amount for an accepted application is not included in neither à la carte or full solution totals

****Note:** The page number differences in the estimate between à la carte and full solution reflect the page, formatting, and content efficiency that a globally unified document can provide. With individually delivered sub-chapters, formatting redundancies and repeat data can increase the final page number.

Facility Safety Plan includes a list of parties which are certified permanent employees or owners who are qualified to handle the hazard that this laboratory facility will possibly face, as well as a list of those specific hazards. Additionally standard control systems and safe practices for these hazards will be stated together with emergency and accident response procedures (a form of an SOP). In parallel with the Operations Plan and Quality Manual are record keeping and employee qualifications for the safety procedures named above. Safety, in the sense used here, refers to any aspect of safety of employees on-site at the facility.

Facility Blueprints and Plans is an integrated blue print designed to set up the equipment, staff positions, and workflow of the lab, tailored to the facility or building that will be hosting the operation. This is an essential element of an application to a state government but also a critical aspect of workplace efficiency. The layout allows the operations to proceed interruption or redundancy, allowing the facilities throughput to increase while decreasing cost.

Facility Operations Plan and Quality Manual is a very large document that essentially outlines how to operate the facility to produce a product of a given quality and how the facility management actively monitors and documents those indicators of quality. Quality, in the sense used here, is any aspect of the product including concepts like food safety and contamination, which can be thought of as consumer safety. This is typically monitored by 3rd party labs. See Appendix B for more details.

Facility SOPs (Standard Operating Procedures) are the written documentation of day-to-day operations. We have used a standard model as an estimate for the structure of the appendix above, which is a facility that extracts its own cannabinoids from flower, and formulates them at known concentrations into two separate products. The facility also has an in-house analysis lab which performs cannabinoid analysis as an in-house verification of the other three facility SOPs.

APPENDIX B

Facility Operations Plan and Quality Manual (example)

- Company Mission Statement
- Organizational Chart of Company
- Scope, Terms, Definitions, and References
- Quality Management System
  - Quality Policy (documentation)
  - Quality Objectives
  - Quality Control

    Internal QC Analysis
    - Potency
    - Training, Qualification and Verification

    External QC Analysis
    - Potency verification
    - Contaminant Analysis (Patient Safety)
  - Qualification and Training Documentation (of staff)
  - Nonconformity and Corrective Action Logs
- Facility Management
  - Quality Policy (implementation)
  - Organizational roles, responsibility, and authority
  - Facility Managers and qualifications
- Facility Staff
  - Facility Staff positions and qualifications
- Facility Operation
  - Facility equipment and instrumentation
  - Facility maintenance, upkeep, and performance verification
  - Facility inventory management
  - Facility Standard Operating Procedures (SOPs)

    Extraction, Formulations, Analysis, Maintenance
- Improvements
  - General improvement planning
  - Nonconformity and Corrective Action Logs

APPENDIX C

Typical formulation SOPs for manufacturers with the necessity of heat as a core component of the formulation indicated.

Matrix	**Formulation and/or Products**	**Heat Req.**
Gelatin	Cannabinoid gummy bears and other similar products	ΔH
Edible Oils	Cannabinoid and Terpene based tinctures and edible formulations	~~ΔH~~
Edible Alcohol	Cannabinoid and Terpene based tinctures and edible formulations	~~ΔH~~
Heavy Oils	Cannabinoids and Terpene based skin products and other topicals	~~ΔH~~
Chocolate	Cannabinoid and Terpene based chocolate products and bars	~~ΔH~~
Vaporizer	Cannabinoid and Terpene based vaporizers which include custom formulations of Terpenes to achieve the desired flavor and psychoactive effects of a desired strain of Cannabis flower, allowing transfer of the consumer experience to a vaporizer or vap pen like product.	~~ΔH~~
Capsules	Cannabinoid and Terpene based oral capsules. Heat may be required to induce psychoactivity, but may be avoided for non-psychoactive (or much less) formulations, such as the cannabinoid acids.	~~ΔH~~
Suppository	Cannabis suppositories that are made for menstrual, reproductive, intestinal, or other relevant issues that been proven effective and popular	ΔH
Baked Goods	Cannabinoid pastries and other similar products	ΔH
Soluble Starches	Sublingual films taken orally under the tongue which have an onset of action of 5-20 min compared to other oral cannabinoids of 60-120 min	ΔH