Standard Operating Procedure		SOP Number: **CC-020-01**
Title: **SOP on SOPs**		Effective:
Prepared by: Date:	Approved by: Ruth	Date:

1. Purpose/Scope

To ensure a consistent process for the creation or revision, review and approval, distribution and implementation of Standard Operating Procedures (SOPs) in compliance with Good Production Practices (GPP).

2. Responsibilities

Quality Assurance Person (QAP)
Quality Assurance Representative

3. Associated Documents

CC-020-F01 SOP Review Index

4. Definitions

Not Applicable

5. References

Access to Cannabis for Medical Purposes Regulations. SOR/2016-230. February 13, 2017

6. Procedure – General Format and Content of SOPs and Forms

6.1. General Format and Content of SOPs and Forms **The SOP Template (Attachment I)** provides an example of generalformat and content of SOPs.

6.2. **The Form Template (Attachment II)** provides an example of general format and content of Forms.

6.3. All SOP and Form page headers will include the company logo or name; document type; Title; Number; and Effective Date. The first page header will also include the preparation and approval name, title, signature and date.

6.4. All page footers will bear the page number in X of Y format and Confidential.

6.5. SOPs and Forms are assigned an alpha numeric code in the following formats:

SOPs: AA-NNN-VV

Forms: AA-NNN-FYY-VV

Where,

AA-NNN Two Alpha and three numbers represents the SOP number;

F Indicates the document is a Form

YY Two-digit number represents the Form number within the parent SOP;

VV The final two numbers specify the version code - "01" represents version new.

6.6. All Forms are associated with a parent SOP and are approved by approval of the SOP.

6.7. All SOPs will include the following sections where applicable:

- *Purpose/Scope* identifies the intent of the SOP and the regions or products to which the SOP applies.
- *Responsibilities* identify the responsibilities of key personnel.
- *Associated Documents*, if applicable identifies related SOPs, Forms, Logs or templates.
- *Definitions,* if applicable
- *References* if applicable, identifies applicable laws, policies, guidelines, etc.
- *Procedure* describes the procedure. Multiple sections are allowed as necessary.
- *Revision History* should include sufficient detail to understand what was changed and brief rationale.

6.8. Where SOPs or Forms are listed or referenced from another SOP, the SOP or Form is identified without the version number.

7. Procedure - Revision and Approval of SOPs and Forms

7.1. New SOPs and Forms are drafted using the templates outlined in *Attachment I and II*, respectively.

7.2. Any individual may propose a new SOP/Form or revision to an existing SOP at any time. Proposals are submitted to the Quality department with the proposed wording provided in any legible format (Word, text, email, or hand- written mark-up).

7.3. A Quality Assurance Representative should review the proposed changes against related regulatory guidelines, SOPs and Quality Agreements to ensure conformance across all Quality documents.

7.4. A Quality Assurance Representative will make a copy of the current version of the Master SOP or Form and save the document with the next version number. The requested revisions to the controlled version of the document may then be made under the new version number.

7.5. The Quality Assurance Representative will review the draft with the original proposal or, if necessary, the draft may be reviewed with the individual who initiated the proposal or other parties, where applicable.

7.6. If the revised SOP (and applicable Forms) is acceptable against the original proposal, a Quality Assurance Representative will print the hard copy in color and sign and date for the Prepared by signage.

7.7. The QAP will approve the SOP by signing and dating the “Approved by” signage.

7.8. When a form is revised the associated SOP must be revised and the Version History updated to reflect the changes to the form.

7.9. The Effective Date should be assigned at least 2 weeks from the date of approval to allow for training.

8. Procedure - Control of Distribution

8.1. An index of current SOPs and Forms will be maintained. The index should be updated as SOPs or Forms are revised. The index is printed and filed with the Master SOP binder.

8.2. The original SOP with signatures and associated Forms are considered the Master SOP and are under the control of the QAP. They are maintained in a labelled binder with Quality. For controlled distribution, only Quality may make copies, stamped "Controlled Copy" in red ink, and signed and dated. Uncontrolled versions are stamped "Uncontrolled Copy."

- A hard copy of all current SOPs is to be maintained in a location accessible to all employees (controlled when required).

8.3. The signed Master SOP or Form is scanned and saved as a PDF file in a dedicated electronic folder.

- Current Forms in PDF format are electronically accessible and may be printed as required. Superseded Forms are moved to an obsolete folder.

- Existing printed forms must be removed from circulation and destroyed once a new form is approved.

8.4. The electronic document corresponding to the Master SOP or Form is saved in a dedicated folder.

8.5. SOPs and Forms are considered confidential and copies will not be provided to third party auditors. Auditors may review the scope-related documents on site.

9. Procedure - Archiving

9.1. To ensure that only the most current version of an SOP is utilized, all superseded Master SOPs or Forms will be marked "OBSOLETE" across the first page.

- Obtain the previous versions of "controlled" copies and replace with stamped "controlled" copies of the most current versions as they become available. The outdated copies are destroyed once received by Quality Assurance.

9.2. All superseded SOPs (signed pdf and Word file) will be retained in the obsolete electronic archive folders.

10. Procedure – Periodic Review of SOPs

10.1. SOPs are reviewed for content at minimum once every two years to ensure the procedures accurately reflect current regulations, procedures and best practices. This review is documented on the SOP Review Index and archived with the controlled version of this SOP. If the review results in recommended updates to a specific SOP, revise the SOP as per section **Error! Reference source not found.**

11. Revision History

Version	Reason for Revision	Date
01	New	

Title: **SOP Review Index**	Doc. Type: **Form**
Document No: CC-020-F01-01	Effective:

SOP / Form Number	SOP / Form Title	Effective Date	Review Date	Changes Required (Y / N)

Approved By: _____ Date: _____

9408843 Canada Inc. Quality