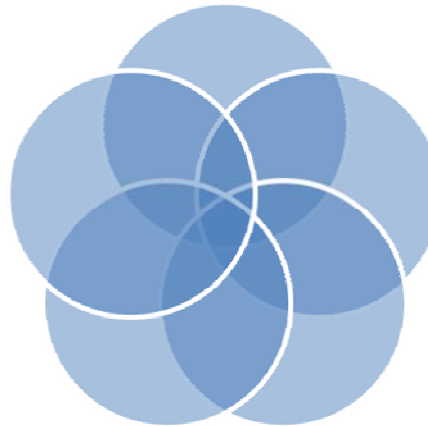


Regulatory Requirements for Natural Products in Canada

Natural Health Products
Directorate

SITE LICENSE
*for Importer &
Manufacturer*



**PRODUCT
REGISTRATION**

SITE LICENSE



Manufacturing Facility must comply with **Good Manufacturing Practices** as laid down by Natural Health Products Directorate, Canada.

Quality Assurance Report (QAR) submission along with supportive documents.

Separate site license for 3rd party manufacturing.

Quality Assurance Report

- GENERAL INFORMATION

- PREMISES:

1. Appropriate spaces and building
2. Prevention of cross-contamination & adulteration
3. Raw Material & Finished Products storage conditions
4. Pest Control

- EQUIPMENT:

1. Designing & construction to prevent cross-contamination
2. Cleaning of equipment
3. Equipment maintenance & calibration

Quality Assurance Report

contd...

- **PERSONNEL:**

1. Education, training & experience
2. GMP training
3. Technical knowledge of Quality Assurance persons

- **PROCESSES & OPERATIONS:**

1. Sanitation program
2. Employee health & hygiene program
3. Material control procedures
4. Critical process controls
5. Self inspection program
6. Inspection programs for contractors
7. Procedures for effective recall of a product

Quality Assurance Report

contd...

- **PRODUCT:**

1. Raw & Packaging materials specifications
2. Finished natural health product specifications
3. changes to product specifications
4. Data from accelerated or real-time stability studies
5. On-going stability program
6. Sample retention program
7. Records maintenance as per the *Natural Health Products Regulations*
8. Procedures for submission of the required information is to Health Canada when a recall is initiated.
9. Manufacturing & packaging of sterile products

Quality Assurance Report

contd...

- STANDARD OPERATING PROCEDURE (SOPs)
- DEVIATIONS AND CORRECTIVE ACTIONS
- SUPPORTING DOCUMENTATION

SITE LICENSE

- If an Indian company has an ISO 9001:2000 certification, NHPD may (!) accept the ISO report (together with the supporting documentation) as GMP evidence.
- While Indian GMP certification can be used in support of the application, it is not sufficient by itself to obtain Canadian GMP certification.

Product Registration

Valid market authorization in Canada:

- Drug Identification Number (DIN)
- Natural Product Number (NPN)
- Homeopathic Medicines Number (DIN-HM)

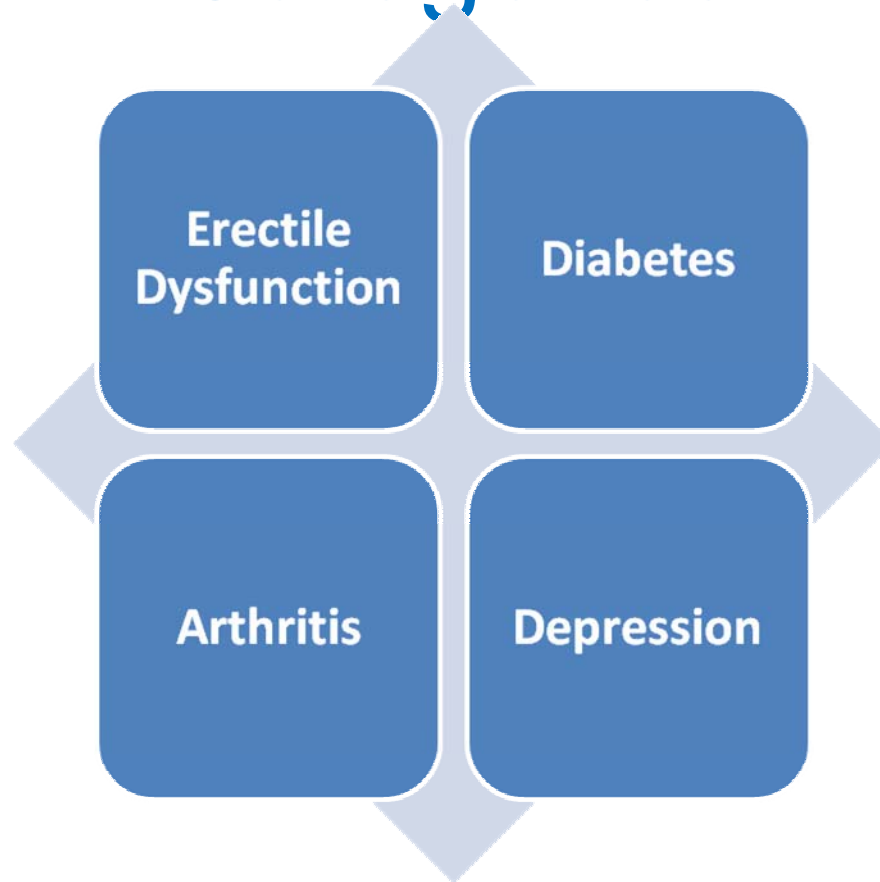
Product Registration

- **Evidence for Safety and Efficacy** of finished natural health products
- The “Compendium of Monographs” can help speed the evaluation of the safety and efficacy of medicinal ingredients commonly used in natural health products. The same is true for "traditional" products.
- If the products fall into the "non-traditional" category, substantial more effort will be required in producing the required regulatory documents.

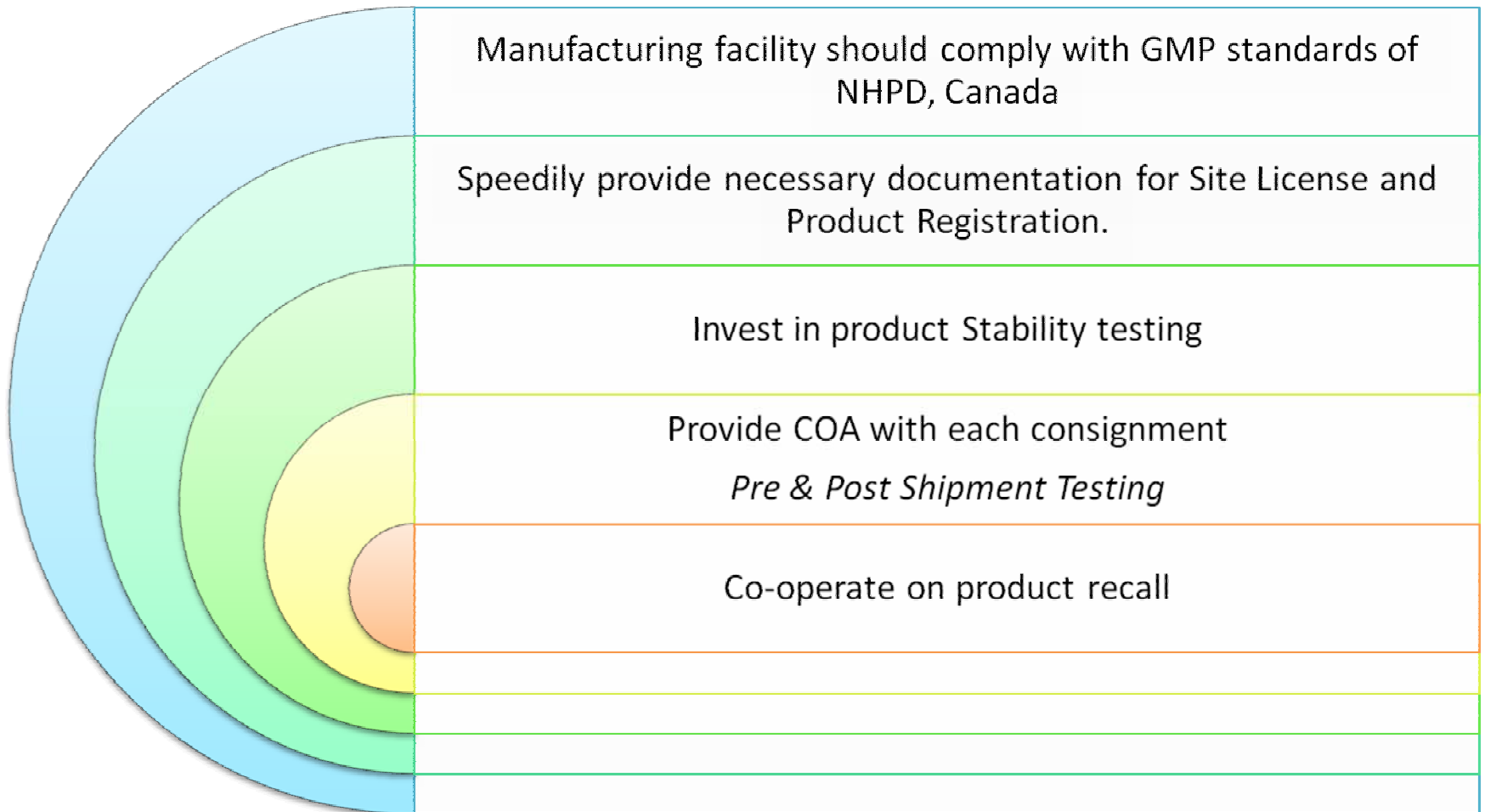
Product Registration

- Stability Data
- Certificate of Analysis to test *Identity, Purity & Quantity*
- Bi-lingual label (English & French)

Potential Therapeutic Categories



Manufacturer's Profile



Manufacturer's Profile

