

Pilot NHP GMP Inspection Program –Survey for Stakeholders Inspected as part of the Pilot

Introduction:

The objective of this survey is for Health Canada to gather feedback on inspection experiences from stakeholders inspected as part of the pilot NHP GMP Inspection Program. Your company was one of 36 companies inspected by Health Canada as part of the pilot.

Your feedback is important as it will help us understand what went well during the pilot and whether changes to processes may be necessary. It also helps us determine future initiatives for collaborating with our stakeholders.

We are hoping that one (1) survey can be completed per company inspected. Please take some time to discuss the survey questions with those personnel who were present during the inspection (including external consultants, if applicable) to ensure you capture the views of all involved.

The completion of the survey should take approximately 10-15 minutes and it must be completed by February 24, 2022. If you experience any technical difficulties while trying to complete this survey, please contact cpab_por-rop_dgcap@hc-sc.gc.ca for assistance.

We encourage you to respond to this **voluntary** and **anonymous** survey. The results will be reported in a formal evaluation of the pilot in aggregate form and responses will not be attributed to specific individuals.

For more information on Health Canada's Privacy Policy, please visit <https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/privacy.html>

Background:

In 2020/21, an [audit of the NHP program was conducted by the Office of the Auditor General \(OAG\)](#). This audit confirmed known gaps in Health Canada's oversight of NHP quality, monitoring of product labels, advertising, and compliance and enforcement. Health Canada accepted all five audit recommendations, which included developing a risk based monitoring and inspection program that establishes the scope and frequency of inspections and that considers risk related to products, sites, and problems raised from its follow-up activities.

On October 27, 2020 and January 11, 2021, Health Canada announced changes to its oversight of regulated activities pertaining to NHPs subject to Part 3 of the [Natural Health Products Regulations \(NHPR\) – Good Manufacturing Practices \(GMPs\)](#).

In February of 2021, a pilot NHP GMP Inspection Program was launched with a plan to inspect 36 Site Licence holders (18 importers and 18 manufacturers). The pilot is now expected to finish the end of March 2022 and the results evaluated.

In line with its ongoing commitment to transparency, Health Canada will post a summary of this evaluation.

As per previous practices with compliance monitoring projects, Health Canada will make every effort to share the results of the pilot with the industry in advance of the publication.

1. Would your company like to participate in this survey?

Select One:

Yes (will advance to survey questions 2-16)

No (will be screened out of survey)

2. Which licensable activity was inspected at your company?

Select all that apply:

- I. Importation*
- II. Manufacturing*
- III. Packaging*
- IV. Labelling*

3. Which type of inspection was conducted of your company?

Select one:

- I. Virtual (completely off-site)*
- II. Hybrid (both virtual and on-site)*

4. Overall, how satisfied was your company with Health Canada's communication on the following topics?

Very dissatisfied –dissatisfied – Neither satisfied nor dissatisfied –satisfied - Very satisfied – Don't know - No Comment

- I. The implementation of the Pilot NHP GMP Inspection Program.*
- II. The history of Health Canada's NHP program and how and why it led to implementation of this pilot.*
- III. My company's regulatory responsibilities as a Site Licence holder.*
- IV. How Site Licence holders would be selected for inspections during the pilot*
- V. What NHP GMP inspectors would examine during an inspection conducted as part of the pilot.*
- VI. When the inspections would be conducted during the pilot.*
- VII. How the inspections would be conducted during the pilot (e.g., virtually or using a hybrid approach).*
- VIII. The time it would take for an NHP GMP inspector to complete an inspection during the pilot.*
- IX. What could cause delays during an inspection.*
- X. What happens at the end of an inspection.*
- XI. What Health Canada intended to do with the results of the pilot.*

5. To what extent does your company agree or disagree with the following statements concerning the NHP GMP inspector's communication about the inspection?

Strongly Disagree – Disagree – Neither agree nor disagree – Agree – Strongly Agree – Don't know – No Comment

- I. The **purpose** of the inspection was clear.
- II. The **scope** of the inspection was clear.
- III. The **length** of the inspection was clear.
- IV. The "Notification of Inspection" issued by the NHP GMP inspector clearly outlined the information the inspector was interested in reviewing.
- V. My company understood that it would receive a report ("Inspection Exit Notice") summarizing the inspection findings.
- VI. My company understood that the NHP GMP inspector would review the draft Inspection Exit Notice with it before finalizing it.
- VII. My company understood the risk ratings assigned to the observations in the Inspection Exit Notice.
- VIII. My company's responsibility to respond to the Inspection Exit Notice with a Corrective Action/Preventive Action (CAPA) plan was clear.
- IX. It was clear what would happen if my company's CAPA plan was submitted late.
- X. My company understood that the inspection was not connected to the Site Licence renewal process and if its Site Licence was due for renewal during the inspection it was still required to submit a renewal package to the Natural and Non-Prescription Health Products Directorate (NNHPD) within 30 days of the Site Licence expiration date.
- XI. My company understood it could receive a notice from the NNHPD regarding an Intent to Suspend or Suspension of its Site Licence or Product Licence(s) as a result of the NHP GMP inspection findings.
- XII. It was clear to my company when the inspection was considered closed, and no further information was required by the NHP GMP inspector and/or NNHPD.
- XIII. It was clear that CAPA responses, considered to be incomplete at the time of inspection closure, would be reviewed at the next inspection or next Site Licence renewal, whichever comes first.

6. To what extent does your company agree or disagree with the following statements concerning the inspector who conducted the inspection?

Strongly disagree - Disagree - Neither agree nor disagree - Agree - Strongly agree - Don't know – No Comment

- I. The inspector was knowledgeable in the subject matter being inspected (e.g., Requirements of Part 3 of the Natural Health Products Regulations; NHP GMP).
- II. The inspector was well prepared.
- III. The overall pace of the inspection was adequate.
- IV. The inspector was easily accessible during the course of the inspection.
- V. The inspector clearly communicated their inspection findings with site personnel.

7. To what extent does your company agree or disagree with the following statements about the virtual platforms used by NHP GMP inspectors to conduct inspections?

Strongly disagree – Disagree - Neither agree nor disagree - Agree - Strongly agree - Don't know – No Comment

- I. The instructions provided for the use of **ePost Connect** to securely share inspection documentation were adequate.
- II. **ePost Connect** was easy to use.
- III. The instructions provided for the use of **VidCruiter** to securely share inspection documentation and communicate with the inspector were adequate.
- IV. **VidCruiter** was easy to use.

8. To what extent does your company agree or disagree with the following statements concerning the NHP GMP Inspection Process.

Strongly Disagree – Disagree – Neither agree nor disagree – Agree – Strongly Agree – Don't know – No Comment

- I. My company had sufficient time to respond to the “Notification of Inspection” issued by the NHP GMP inspector.
- II. My company had sufficient time to prepare for the inspection.
- III. My company had sufficient time to discuss the inspection findings with the inspector before the inspection report (“Inspection Exit Notice”) was finalized and issued.
- IV. My company had sufficient time to provide a CAPA plan.
- V. My company learned a lot about its regulatory responsibilities during the course of the NHP GMP inspection.

9. My company's knowledge of its regulatory responsibilities BEFORE it was inspected was:

5-point scale with anchor points: 1-Not at all knowledgeable/2/3/4/5 –Extremely knowledgeable

10. My company's knowledge of its regulatory responsibilities AFTER it was inspected was:

5-point scale with anchor points: 1-Not at all knowledgeable/2/3/4/5 –Extremely knowledgeable

11. Has your company's knowledge of NHP GMPs increased as a result of the NHP GMP Inspection?

Select one:

Yes

No [Skip to Q11]

Don't know [Skip to Q11]

No comment [Skip to Q11]

a. Please describe in what way(s) your company's knowledge of NHP GMPs increased:

[Text Answer]

12. Is there an area of NHP GMP, which still remains unclear to your company?

Select one:

Yes

No [Skip to Q12]

Don't know [Skip to Q12]

No comment [Skip to Q12]

a. Please indicate which part(s) of the NHP GMP remain unclear and why:

- i. Prohibition (Section 43 of the NHPR)
[Text Answer]
- ii. Specifications (Section 44 of the NHPR)
[Text Answer]
- iii. Premises (Section 45 of the NHPR)
[Text Answer]
- iv. Equipment (Section 46 of the NHPR)
[Text Answer]
- v. Personnel (Section 47 of the NHPR)
[Text Answer]
- vi. Sanitation Program (Section 48 of the NHPR)
[Text Answer]
- vii. Operations (Sections 49 & 50 of the NHPR)
[Text Answer]
- viii. Quality Assurance (Section 51 of the NHPR)
[Text Answer]
- ix. Stability (Section 52 of the NHPR)
[Text Answer]
- x. Records – Manufacturers (Section 53 of the NHPR)
[Text Answer]
- xi. Records – Packagers (Section 54 of the NHPR)
[Text Answer]
- xii. Records – Labellers (Section 55 of the NHPR)
[Text Answer]
- xiii. Records – Importers (Section 56 of the NHPR)
[Text Answer]
- xiv. Distributors (Section 57 of the NHPR)
[Text Answer]
- xv. Record Maintenance (Section 58 of the NHPR)
[Text Answer]
- xvi. Sterile Natural Health Products (Section 59 of the NHPR)
[Text Answer]
- xvii. Ophthalmic Use (Section 60 of the NHPR)

[Text Answer]

- xviii. Lot or Batch Samples (Section 61 of the NHPR)

[Text Answer]

- xix. Recall Reporting (Section 62 of the NHPR)

[Text Answer]

13. Overall, what went well during the inspection process?

[Text Answer]

14. Please share any other comments, ideas or suggestions your company would like Health Canada to consider for improvement of the NHP GMP Inspection Process.

[Text Answer]

15. Please share any other comments, ideas or suggestions your company would like Health Canada to consider if a permanent NHP GMP Inspection program is implemented.

[Text Answer]

16. Please share any other comments that your company would like Health Canada to consider.

[Text Answer]

Thank you for taking the time to complete this survey!