

17 October 2023

TO BE AUDITED OR INSPECTED – A PRACTICAL PV TRAINING

Full day in-person training +
1-hour personalized consultation
(in Swedish)

**Do you want to build skills and
confidence to lead yourself and
your organization through a PV
audit or inspection?**

TO BE AUDITED OR INSPECTED – A PRACTICAL PV TRAINING

To be audited and inspected is something everyone working within Pharmacovigilance will be exposed to, at one point or another. In this situation it is all about being able to present your company's PV system in a way that shows that patient safety is ensured at your company, and how you do it. **So how can we build skills and confidence to do that?**

As we see it, audit and inspection readiness is all about being both mentally and practically prepared.

This is why our PV experts have developed this interactive training, where you practice real life situations relevant for your own role. You will get the opportunity to explore different scenarios of the pre-audit/inspection and conduct, in a safe and calm setting. Our trainers Lena and Ann-Marie have experience from roles as auditor and inspector. They have also been in the situation of being audited and inspected. By sharing their experience and competence they will guide you through the training day's exercises.

What you will learn:

- **Practice** to present your area of expertise and see what works well and what works less well. Get feedback including examples of request within your area.
- **Understand** what you can prepare and do to be more audit/inspection ready, both mentally and practically.
- **How to assess** your gaps/deviations in advance in order to be pro-active and prepared.
- **Critical considerations** when replying to audit/inspection request.
- **Understand why** the auditor/inspector requests specific items, what they are looking for and how they are using the information.
- **Understand what** an inspector/auditor expects and how they work, by putting yourself in their situation.



Target group:

You work with or together with Pharmacovigilance and Drug Safety at a head quarter or affiliate.

You are a vendor/service provider. You want the PV-audit situation to be less stressful. You who might feel practically prepared but never had the chance to practice on the actual conducting parts.

Course set up:

Preparation before the session: You will be provided with pre-read material on audits and inspection definitions, such as the audit universe, legal requirements, audit types, audit strategy and program, and different roles in an audit/inspection. You are asked to prepare a 5-minute presentation of your PV area, to practice this element in a small group. Finally, an optional task consisting of collating certain data in advance to the course, which will be discussed during the course. More detailed instructions will be sent out well in advance.

During the session: We are using a dynamic approach in our training, with practical exercises, alongside with discussions on what this means in practice. You will also receive useful materials to help you apply your learnings back in your office.

After the session: The 1-hour personalized consultation is the perfect complement to this training. Our PV team will join you digitally or physically to discuss current issues or how to apply the learnings you obtained during the sessions in your own organization. Maybe you need strategic PV advice or, if you are new or alone in your PV-role, you might rather prefer an hour mentoring with an PV-expert. Contact us within 15 days after the on-site training to schedule this personalized 1 hour session.

Agenda:

09.30-10.00 *Optional meet and greet trainers and participants (coffee)*

10.00-12.00 Workshop focus: Audit/Inspection Preparation /Readiness

12.00-13.00 Lunch

13.00-16.45 Workshop focus: Audit/Inspection conduct

16.45-17.15 *Optional meet and greet PharmaRelations (sandwich)*



Standard fee:

6.900 SEK (exc. VAT)

The fee includes pre-read materials, templates and handouts, a course certificate, lunch and coffee/refreshments during the day.

Groups of 4 or more people and organizations with frame agreements with PharmaRelations can obtain a special price.

Date:

Tuesday October 17,
2023

Time:

10:00-16:45 hrs + 1 hour
consultation

Language:

Swedish

Location:

Frösundaviks Allé 1
Stockholm

Scan the QR to
register and read
the course outlay
or at:



pharmarelations.com/academy/audits

Meet the Trainers

Lena Ternrud has more than 4 years of experience from competent authorities as a Pharmacovigilance Inspector at the MPA. She has worked 14 years with Pharmacovigilance, and her previous experience also includes medical information, regulatory affairs, and quality assurance.



Ann-Marie Hjemgaard has extensive knowledge and experience of pharmacovigilance processes from working 22 years in different PV roles within the pharmaceutical industry. She also has an extensive knowledge and experience of Computer System Validation of GxP PV systems, data integrity and data privacy.

Both Lena and Ann-Marie work as Senior Pharmacovigilance Specialists at PharmaRelations, where they perform PV and CSV audits as well as QPPV and Deputy QPPV assignments.