Dear all,

We are excited to get our new PV Audit Network up and running!

Thursday, 1 October 2026, 15:00–17:00
Hosted by Ascendis Pharma in Hellerup

Agenda for our first meeting

1. Welcome & Roundtable – 45 min

A brief introduction from each participant/company, including:

- How many PV partners do you work with?
- How many affiliates do you have?
- How many PV auditors are there in your organization?
- What is your professional background and audit experience?
- What do you hope to gain from this network?

2. New EMA Requirements Regarding Audits of Subcontractors – 30 min

Discussion topic:

- How have you implemented the new requirements in your SOPs and PV Audit Program?

3. PV Audit Risk Assessment – 30 min

How do you approach risk assessment for:

- Affiliate audits?
- Process audits – which processes do you include, and how do you define/scope the individual process audits?

4. Any Other Business (AOB) – 15 min

- Topics and agenda for the next meeting
- Meeting frequency – we propose **three meetings per year**

David from Ascendis has kindly offered to provide coffee and cake

Meeting format

Face-to-face

Conducted in English

Parking

In front of Ascendis Pharma (very limited)

At the Waterfront Shopping enter (payment needed)

Bus

1A