

Training

Infarmed's experience

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Type of training / educational activity

First part

- o Basic training.
 - on the principles of the EU regulatory system for medicines
 - on the available sources of relevant information

Type of training / educational activity

Second part

On-the-job training

- Trainee participates in the day-to-day activities of the training area (e.g. management of MA / post MA procedures, for national/CMS and RMS procedures).
 - All the activities are supervised by a member of the staff
 - Attendance of a plenary meeting of the Committee for the Evaluation of Medicines (assessors' meeting)
 - All the trainees have to fulfil the same criteria as Infarmed's employees in terms of Declaration of Interests and Confidentiality

Rational behind the initiative

o Target audience:

- Training programmes which are part of the graduation in pharmaceutical sciences, and the trainees are finalist students or
- Trainees have already a degree in pharmaceutical sciences, and present a proposal for an individual professional traineeship

o How long has this been in place:

- There have always been trainees at Infarmed, although recently the number of candidates has increased exponentially

Rational behind the initiative

- **Type of interaction with regulators (national and EMA) for content delivery, if any:**
 - Since the trainee is involved in the same activities as the internal staff, the interactions are the same
 - All the activities are supervised by a member of the staff
- **Added value for participants:**
 - The knowledge acquired during the training

Key lessons learnt that could be shared with other organisations

- Need to establish a minimum duration (*6 months full time or 1 year part-time*)
- Need to set dates for the start of traineeships (*4 times per year*)
- Need to define the profile of the trainee (*background training*)
- Need to define a basic training programme (*per area of regulatory activity*)
- Need to be very clear on which activities can be performed by a trainee
- Need to establish how to measure performance of the trainee
- Need to clearly identify the member of the staff who is responsible for the trainee (and the performance indicators of this member of staff should reflect this)

Thank you!

Please see also:

www.infarmed.pt

<http://m.infarmed.pt>



https://twitter.com/INFARMED_IP



<http://www.linkedin.com/company/infarmed>