

Curriculum Vitae

Personal information **Dorota Distlerova**

Work experience

1. Employer: State Institute for Drug Control
 - Start date: 11/2021
 - Position: Head of Quality Assessment Office
 - Activities:
 - leading a team of quality assessors who assess pharmaceutical quality for MAAs and variations, allocation of work (national, decentralised, centralised procedures)
 - review and quality check of assessment reports, assessment work
 - drafting and amending of SOPs, drafting and improvement of internal procedures for assessment and for the use specific tools
 - training and knowledge sharing in the team, supporting each team member as necessary in their work and in coping with assessment and other work-related issues they come across, troubleshooting
 - reporting to the Head of Regulatory Section and the Head of Agency
 - responding to freedom of information requests
 - contribution to legal output of the agency, as necessary
 - as of 03/2020 in the position of QWP member for Slovakia: reporting on the work of the working party internally in the team and to the management of the agency
 - as of 05/2020 in the position of CHMP alternate: reporting on the quality-related assessments
 - Country: Slovakia
2. Employer: State Institute for Drug Control
 - Start date: 06/2018
 - End date: 11/2021
 - Position: Quality Assessor
 - Activities:
 - critical assessment of pharmaceutical quality of MAAs, variations (centralised, decentralised, national) and ASMFs, assessment of product information
 - pioneering of assessment of centralised procedures and applications for new active substances in the agency, presentation of issues with centralised applications at the QWP core team meetings
 - responding to queries with regard to the legal basis, variation classification, freedom-of-information requests and other ad-hoc queries
 - Country: Slovakia
3. Employer: Pharm-In, s.r.o.
 - Start date: 06/2017
 - End date: 06/2018
 - Position: Regulatory Affairs Manager
 - Activities:
 - acting on behalf of marketing authorisation holders and applicants in terms of regulatory submission to the NCA in Slovakia, such as submission of applications, communication with the agency, handling of decision letters, issued by the agency
 - product information check
 - provision of regulatory intelligence, responding to queries with regard to the legal basis, variation classification and other ad-hoc queries of the MAHs
 - Country: Slovakia
4. Employer: Medicines & Healthcare products Regulatory Agency (MHRA)
 - Start date: 10/2015
 - End date: 05/2017
 - Position: Pharmaceutical Assessor (Licensing Division)
 - Activities:
 - critical assessment of pharmaceutical quality of MAAs, variations (decentralised, national) and ASMFs, assessment of product information
 - overview of procedures within the assessment teams
 - compilation of papers for plenary meetings of the Commission on Human Medicines (CHM) and Expert Advisory Committees, presentation of papers at the committee meetings
 - responding to queries with regard to the legal basis, variation classification, freedom-of-information requests and other ad-hoc queries
 - Country: United Kingdom
5. Employer: European Medicines Agency (EMA)
 - Start date: 10/2014
 - End date: 09/2015
 - Position: Trainee
 - Activities:
 - contribution to and finalisation of CHMP Assessment Reports, compilation of other supporting documents related to assessment of MAAs and variation applications submitted through centralised procedure
 - conduct of a project on approved indications in paediatric rheumatology and extrapolation of data employed in this therapeutic area, poster presentation, contribution to the internal awareness session on this topic
 - Country: United Kingdom
6. Employer: State Institute for Drug Control
 - Start date: 09/2013

- End date: 09/2014
- Position: Procedure Manager
- Activities:
 - post-authorisation procedure management of medicines for human use (variations to marketing authorisations of all types, renewals and transfers) within NCA
 - compilation of comments within mutual recognition and decentralised variation procedures
 - coordination of Quality, Non-clinical and Clinical assessment
 - product information and mock-up review, linguistic check of PI of centrally authorised products
 - post-authorisation procedure training of new starters
- Country: Slovakia

Education and training

1. Subject: Faculty of Pharmacy, Comenius University
 - Start date: 09/2013
 - End date: 09/2014
 - Qualification: Doctor of Pharmacy
 - Organisation: Comenius University, Bratislava
 - Country: Slovakia
2. Subject: Faculty of Pharmacy, Comenius University
 - Start date: 09/2008
 - End date: 05/2013
 - Qualification: Master of Pharmacy
 - Organisation: Comenius University, Bratislava
 - Country: Slovakia

Additional information

Publications

Stefanska AM, Distlerová D, et al. Extrapolation in the development of paediatric medicines: examples from approvals for biological treatments for paediatric chronic immune-mediated inflammatory diseases. Arch Dis Child. 2017 Oct;102(10):952-957. doi: 10.1136/archdischild_2016_312259.

Projects

Memberships

Other Relevant Information