



The State Institute for Drug Control opens the position of:

Head of Marketing Authorisation Branch

The Marketing Authorisation Branch ensures granting of marketing authorisations to all proprietary medicinal products marketed in the Czech Republic. The marketing authorisation procedure includes, in particular, the assessment of provability of quality, safety and efficacy of products, the assessment of indications, contraindications, posology, and classification for supply; the product information evaluation for correctness and completeness, the approval of packaging, evaluation of proposed variations to already marketed medicinal products. Besides the above listed procedures the Marketing Authorisation Branch issues opinions on borderline products and applications for specific therapeutic programmes, clinical trials and also keeps records of non-authorised medicinal products use.

Position profile:

The Head of Marketing Authorisation Branch is responsible for:

- ensuring comprehensive activity, organisation and management of the branch
- organisation of marketing authorisation-related work, design and optimisation of marketing authorisation processes, effective work managements and economic management of the branch
- identification of development and trends in the regulated area
- proposals and realisation of measures to meet the tasks of the branch in relation to changes in environment and legislation

furthermore, the Head of Marketing Authorisation Branch

- participates in drafting legal regulations both at national and EU level
- makes proposals for strategic conceptual plans in the area of authorising medicinal products for marketing
- actively cooperates with the EU regulatory authorities in the area of marketing authorisations
- represents the Institute in negotiations with customers and partners

Qualification requirements + specific skills:

- university degree, university degree in human medicine, veterinary medicine or pharmacy is an advantage
- professional experience in regulatory affairs min 6 years, of which at least 2 years in a managerial position
- international experience in regulatory affairs an advantage
- fluency in English, knowledge of Czech an advantage
- communication, presentation and organisational skills
- strong and highly motivated personality, initiative approach to innovation, result-oriented personality



To apply for this position, send your:

- Structured CV
- Details of previous experience including job descriptions / responsibilities in previous positions
- Motivation letter giving your reasons for interest in this position and key ideas for branch management, main targets and long-term strategies
- Signed declaration in writing:

Declaration of candidate:

I hereby declare that all the information given above is true and complete to the best of my knowledge. I agree with processing of my personal data stated in this questionnaire in SUKL job candidates database. In the case that I am not appointed to this position I agree/don't agree that my data are kept in the candidates database for 12 months. In the case that an employment contract is concluded with me I hereby give consent to inclusion of this questionnaire in my personal file.

You are invited to submit your application until 15th December 2011 at the latest.

Terms of employment:

- Date of commencement upon agreement
- Employment contract by appointment, with 3-months probation period, for a fixed period of one year
- Competitive remuneration corresponding to high demanding job
- Employee benefits
- Opportunity for career growth and professional and managerial training

Contact:

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