

## pharmaceutical translation

# Drug discovery and development

## Maria José Dias Wyborn attends a course for translators to find out more about this fascinating and complex world



Maria José Dias Wyborn holds a degree in Chemical Engineering and a PhD in Hydrometallurgy from Imperial College, London, and worked in Mozambique. South Africa, Brazil, USA and Portugal before starting a career in technical and scientific translation in the UK

new medicine takes on average 10 to 15 years to develop at an average cost of about \$800 million to \$1 billion. The R&D carried out by pharmaceutical companies in the UK costs about £10 million a day. It may be necessary to research 5,000-10,000 compounds to treat a disease, and ultimately only one will receive approval. Statements like these give a brief glimpse of the importance of the world of drug discovery and development. They also serve to reinforce the need for documentation to be translated.

It is often hard to find an expert to provide translators with a condensed, yet thorough, explanation of basic concepts and the procedures that have to be followed up to the launch of a product. Fortunately, that is not the case for translators who work, or wish to work, in pharmaceuticals and who want to develop a sound knowledge of this field.

Through the North-West Translators Network I attended a oneday course in Manchester entitled 'How the Drug Discovery Industry Works', delivered by Dr Ed Zanders, founder of ScienceInform.

ScienceInform Ltd. specialises in training in the scientific aspects of healthcare and aims to make pharmaceutical jargon accessible. Dr Zanders has a PhD in biochemistry, spent 16 years at Glaxo as Senior Research Manager, and worked for small biotech start-ups. He is able to deliver the subject with ease and skill, based on his own experience.

#### **Small beginnings**

And so the course started with the very simple concepts of atoms and molecules and developed through the explanation of what a drug and a drug target are. Drugs are molecules which can have a molecular weight of less than 500 or as large as hundreds of thousands. A drug target is also a molecule within the organism that is linked to a particular disease and whose activity can be affected by the use of a drug (another molecule). It is the identification and validation of a drug target for a particular disease, therefore the understanding of the disease itself, which is crucial for the development of a new medicine by discovering the right molecule (potential drug) to interact with a validated target. An explanation of human physiology and pathology followed, and the concept of receptors, agonists and antagonists was introduced. Different types of drugs offered by the pharmaceutical industry were discussed, ranging from pills to injected hi-tech biotech products, and the terminology of biotech medicines was covered in some detail. At this point these concepts were consolidated with the presentation of a case history - the development of an anti-ulcerant drug.

After learning how pharmacology has led to the development of many medicines in current use, we moved on to the 'drug discovery pipeline'. This is the activity that starts with the identification of the drug target and finishes with the clinical testing and

launch (marketing) of the drug. As many as 5,000 to 10,000 compounds are tried at lab scale, a process that might take three to six years. Many of these will be immediately abandoned and only a few hundred will make it to the next phase, preclinical testing, involving various studies in the lab and with animals. This phase will eliminate most of the candidates, and only five out of the initial number of active compounds will be tested in clinical trials. These are divided into four phases: Phase I, Phase II, Phase III and Phase IV or Post-marketing phase. In Phase I the candidate drugs are tested in a small group of healthy volunteers to discover if the drug is safe in humans. The next two phases involve the testing of the candidate drug on an increasing number of patients with the disease to observe effectiveness, side effects and risks, and ultimately to confirm effectiveness, determine the overall benefit/risk relationship of the drug and monitor adverse reactions from long-term use. Throughout these three phases, which last from six to seven years, the number of candidates is reduced to only one. In Phase IV additional testing is carried out, if required by the FDA, and the newly licensed medicine is studied in a large number of patients in general practice.

### **Help is at hand**

Other aspects of the pharmaceutical and biotechnology industries were also presented, and glossaries and other reference material were provided (clinical terms, acronyms, definitions and abbreviations). Knowledge of these is essential in an industry with a vast scientific vocabulary and a fondness for acronyms.

With this article I hope I have raised awareness that help is at hand in the form of this course for those who want to learn more about the pharmaceutical industry. In my view it is a must for translators moving into the pharmaceutical translation field or those who need to add to their existing knowledge. I hope that other courses will follow that address other subjects, such as clinical trials.

Details of this and other courses can be found on the ScienceInform website: www. scienceinform.com or by contacting Dr Ed Zanders at ed.zanders@scienceinform.com

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