Welcome to Pharmaceutical Methods

I would like to welcome you to the first edition of Pharmaceutical Methods, my name is Ambrose Furey and I am a natural product chemist with a speciality in mass spectrometry and with an interest in matters pertaining to quality assurance and method validation in the regulatory environment.

As you can see from the diverse array of articles in this first issue, the journal aims to be of broad scope and is intended to stimulate innovation in all matters pertinent to the pharmaceutical area. The journal aims to publish a diverse and interesting mix of articles ranging from approaches to drug development strategies, to analysis of key components and contaminants, to validation strategies and also new approaches to the setting up or the development of QA management systems. Therefore, this journal will provide a forum for sharing interesting and valuable information among those associated with the pharmaceutical industry and those in academia.

Let us look at the complexity of one aspect of pharmaceutical endeavour: drug development. Every year thousands of molecules are tested as potential drug targets owing to a demonstrated bioactivity often established *in vitro* with a potential to arrest or disrupt the progression of disease. However, identifying a potential drug is just the start of a long and arduous road where many promising compounds are abandoned *en route*. The first step in the process always involves chemical characterization of the molecule (often isolation or synthesis, purification, LC or GC hyphenated with MS/MS to determine size, NMR to elucidate structure); conditions for optimum biological function of the compound must be discerned and then the extensive and conclusive testing to determine its toxicity, bioactivity *in vivo* and of course its mechanism of action and its bioavailability. Often activity is chemically modified or enhanced using combinatorial synthetic approaches.

If the compound is still showing some pharmaceutical potential after these stages, then researchers must determine a stable and effective formulation for drug delivery. Frequently animal models are used to conduct absorption, distribution, metabolism and excretion (pharmacokinetic) studies. At this stage, using two or more mammalian species, intensive acute studies (24 h duration; to ascertain toxic dose levels), repeated dose studies (to establish chronic toxicity), genetic toxicity studies (to detect DNA damage/changes), reproductive studies and carcinogenicity studies (for drugs intended for use in the treatment of chronic conditions) must be conducted. Of course in themselves animal models cannot be assumed to be absolute predictors of human response, later on during clinical trials these data will be re-evaluated.

Now imagine all of the above testing must be conducted in parallel with adherence to the strictest regulations and in tandem with rigorous bio analytical work (a topic explored in this issue by Pandey *et al.*). The bio analysis is critical for each stage of the development process and also to support phase 1 and phase 2 clinical trials later; the methods deployed must be validated in compliance with the most meticulous and uncompromising quality assurance requirements. Following these lengthy processes, the next step is clinical trials where human response is investigated; this is overseen scrupulously by the FDA, ethics committees and regulatory bodies. It is normally a three stage process: stage I investigates human pharmacology using healthy volunteers; stage II examines drug efficacy in *ca* 200+ patients; stage III assesses safety and efficacy in large patient populations; finally license applications are prepared and submitted to the relevant authorities.

As we look at the process of drug development and we envision the additional requirements that bulk manufacturing demands, we can see the enormity of the undertaking and we can discern the multitude of auxiliary supports and resources necessary for this industry. We must also be impressed by the imperative for safety because the ultimate objective is to treat human beings. The impetus for this journal is to tie together the myriad of components involved in the pharmaceutical process and to stimulate and share advancements in the area.

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