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# Book Review

## In vitro-in vivo correlations

At a recent meeting it was stated that the regulatory guideline 'Quality of Prolonged Release Dosage Forms' which demands the development of in vivo-in vitro correlations for such products was probably the most ignored guideline produced by the Committee on Proprietary Medicinal Products (CPMP). There was speculative discussion about why this might be and contributory factors were considered to be lack of guidance of how such correlations should be developed and lack of understanding on the part of the applicant company of the use of such correlations.

It was against this background that I picked up this book, a collection of contributed articles and papers produced from posters presented at a meeting entitled 'In vitro-In vivo Relationship Workshop' organised by a co-operative working group which includes members from a drug delivery company and academics from both sides of the Atlantic.

In a review of this type of monograph, which contains a large number of articles it is probably not very constructive to outline all of the contributions especially as they encompass such a broad overview of the topic. Articles range from a basic discussion of the quality of in vitro-in vivo correlation, a very useful introduction, with more detailed discussion of some of these approaches such as convolution techniques, through more complex treatments such as non-linear correlations, atypical neural networks and very interesting, illustrative examples of the use of correlation in manufacture and testing of modified release forms. As an aside, although I do not think that non-linear correlations are very useful, in the light of the valid criticism that many 'linear' correlations show some curvature, the use of non-linear mixed effects modelling looks promising.

It is not surprising, given the composition of the working group that the emphasis of the contributions are American rather than European. Thus the 'Draft Guidance for Industry' is geared rather specifically to the FDA guidance on Scale Up and Post Approval Changes (SUPAC) although the principles merit general application.

The primary European issue currently is the development of dissolution specifications (including retest criteria) which can be justified by correlation to ensure consistent in vivo performance. This is encompassed within the guide and more specifically in an article by Piscitelli and Young, which should be read by all contemplating a European Marketing Authorisation application.

It is unfortunate that the authors have tried to cover all areas because the book would have lost nothing by the omission of the text on the role of correlations to Regulatory Agencies especially as the information concerning Europe is not only cursory but also grossly inaccurate.

Nevertheless, this is a book which should be compulsory reading for all with an interest in modified release preparations, and if this were so, the CPMP guideline referred to earlier hopefully would have more enthusiastic compliance.

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