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PREFACE

This book represents the invited presentations and some of the posters presented at the conference entitled "*In Vitro-In Vivo* Relationship (IVIVR) Workshop" held in September, 1996. The workshop was organized by the IVIVR Cooperative Working Group which has drawn together scientists from a number of organizations and institutions, both academic and industrial. In addition to Elan Corporation, which is a drug delivery company specializing in the development of ER (Extended Release) dosage forms, the IVIVR Cooperative Working Group consists of collaborators from the University of Maryland at Baltimore, University College Dublin, Trinity College Dublin, and the University of Nottingham in the UK. The principal collaborators are:

Dr. Jackie Butler, Elan Corporation
Prof. Owen Corrigan, Trinity College Dublin
Dr. Iain Cumming, Elan Corporation
Dr. John Devane, Elan Corporation
Dr. Adrian Dunne, University College Dublin
Dr. Stuart Madden, Elan Corporation
Dr. Colin Melia, University of Nottingham
Mr. Tom O'Hara, Elan Corporation
Dr. Deborah Piscitelli, University of Maryland at Baltimore
Dr. Araz Raoof, Elan Corporation
Mr. Paul Stark, Elan Corporation
Dr. David Young, University of Maryland at Baltimore

The purpose of the workshop was to discuss new concepts and methods in the development of *in vitro-in vivo* relationships for ER products. The original idea went back approximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development. It was obvious that more and more of our time was spent discussing issues and aspects of IVIVR development since it plays such a key role in dosage form development, particularly for ER products. We felt it was important to provide a forum where scientists from industry, academia, and regulatory authorities could come together and discuss how best to develop methods in this complex area.

It is also important to emphasize and appreciate the background and context of the workshop. One can readily identify major milestones and initiatives over the last 10 years that have contributed significantly, either directly or indirectly, to the development of IVIVR methodology. In the last 5 years, the pace of these initiatives has accelerated, very much driven by the FDA. In particular, one can identify the SUPAC IR and ER Work-

shops of the early 90s, resulting in the 1995 issuance of the SUPAC IR guidance, with additional draft guidances prepared during 1996. In the context of IVIVR this has culminated in the issuance of the FDA draft guidance on IVIVC, which was completed just prior to the workshop.

At the point where we set a date for this workshop, we did not anticipate being so timely in relation to the issuance of the draft guidance. However, we believe that the discussions and ideas generated during the workshop provided a better understanding of the guidances and gave valuable feedback to the agency in what was the first public forum since the issuance of the guidance.

As one point of clarification, the Cooperative Working Group, who organized this meeting, talk about IVIVR. Many of the speakers and, indeed, the FDA draft guidance, referred to IVIVC. For the purposes of this workshop, these terms were viewed as interchangeable.

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