Book Review: Biological Safety & European Medical Device Regulations

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The author states that the primary purpose of this book is to provide guidance for manufacturers, regulators and others on performing a toxicological risk analysis and evaluating and controlling any identified risks. Chapter 2, *Biological Safety and Regulation*, should be informative and interesting reading for anyone, including consumers, wishing to understand the biological safety requirements and the current state-of-the-art of assuring these requirements for medical devices. The subsequent chapters describe what responsible manufacturers, regulators and Notified Bodies should consider when assessing and documenting the biological safety of medical devices.

One of the common misconceptions of the Essential Requirements is that Number 7.5 ('The devices must be designed and manufactured in such a way as to reduce to a minimum the risk posed by substances leaking from the device') means that economic factors and device availability play little or no role in device approval. The author points out that the principles of the Essential Requirements do not view risk in absolute terms and that 'state-of-the-art' is used in assessing an adequate level of safety.

Many regulatory authorities make significant use of biological safety standards for judging and assuring the acceptability of approved medical devices. The author directs attention to the fact that current standards describe methods of biological testing, but are virtually deficient in describing how the results should be evaluated and used to establish product safety. Table 3, pages 16–17, reveals some of the strengths and weaknesses of the ISO 10993 series of standards for demonstrating conformity with Essential Requirements and assessing biological safety. Chapter 4, *The Elements of an Assessment Programme*, discusses in more detail the pros and cons of many of the ISO 10993 standard tests. The author also indicates in several sections of the book that the tests outlined in EN/ISO 10993-1 are often viewed as a required test list, resulting in unnecessary and expensive testing, when in reality the only normative requirement is that the rationale for conducting or waiving a test be recorded.

In several sections, the author reminds readers to take a practical approach to evaluating the biological safety of medical devices. For example, he repeatedly points out that materials characterisation data can often decrease the biological testing required. Although the casual reader might interpret some discussions as advocating *in vitro* over *in vivo* tests, the author also points out in other discussions that the *in vivo* reaction is the sum of many individual interactions of which we do not have detailed knowledge of the role of the individual elements. When biological testing is required, the difference between toxicity tests and 'biocompatibility' tests is discussed. The author also indicates that, in general, the more sensitive the test the more reliable it will be for hazard identification, but less specific at characterising the risk. These are insights that are often not understood or neglected by those responsible for assessing the biological risk associated with the use of a medical device.

Chapter 6, *Judging Safety and Demonstrating Conformity*, describes how to reach a decision on the acceptability of the risks associated with a medical device. It is a thorough discussion of the criteria and parameters that must be considered. Because

many of these elements are qualitative rather than quantitative, it becomes evident that parties responsible for assuring that an adequate level of safety might disagree on the final decision, particularly when a device falls into the boundaries of the ALARP (as low as reasonably practicable) and the intolerable regions.

Although I have experience in many aspects of biological evaluation of the safety of medical devices, this book will serve as a reference document that I will consult to improve my understanding of many of the regulatory and scientific considerations that should be explored when judging the safety of medical devices.

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[The views expressed in this review should not be construed as official policy of the US Food & Drug Administration.]

On the Move...

Professor Aidan Halligan has been appointed as the new Chief Executive Officer for the **Irish Health Service Executive** and will take up the new post in April 2005. Professor Halligan is currently working as Deputy Chief Medical Officer for the UK's Department of Health.

On 1 October 2004, it was announced that **Hermann Wilhelm Ahls** had been elected as the new Secretary General of the **European Committee for Standardization (CEN)**. In his new role, Mr Ahls will head the CEN Management Centre and administer the daily work of the organisation to ensure that it fulfils its objectives as set by the Administrative Board.

The **American College of Clinical Engineering** (ACCE) has appointed **Izabella Gieras** as President for the 2004/5 term. Ms Gieras, who most recently served as ACCE's president-elect, is a senior clinical engineer with Beaumont Services Company LLC in Royal Oak, MI, USA. Other newly appointed ACCE officers include President-Elect Steve Grimes, Vice President Ron Baumann, Treasurer Joe Skochdopole and Secretary Colleen Ward.

James Schlicht is the new Chief Government Affairs & Advocacy Officer at the **American Diabetes Association**. This is a new position within the Association and Schlicht will be responsible for healthcare policy formulation including developing strategies to improve insurance coverage and healthcare for people with diabetes, ending discrimination against those with the illness, and increasing federal funding for diabetes research and prevention.

In the biotechnology arena, **Thomas M Finneran** became the President of the **Massachusetts Biotechnology Council** on 4 October 2004 and **G Steven Burrill** was appointed as Chairman of the newly formed **San Francisco Mayor's Biotechnology Advisory Council** (MayBAC).