

# Dr. rer. nat. Mark Smith

since 2021      *Senior Advisor ATMP Manufacture and Quality Assurance*  
Muscle Research Unit, Charité Universitätsmedizin Berlin and the Max  
Delbrück Center for Molecular Medicine in the Helmholtz Association,  
Berlin, Germany

## Experience and Education

2006 – 2020      Senior positions in Pharmaceutical Product Development and Manufacture:  
Head of Biotechnology, Head of R&D, Head of Manufacturing, Senior  
Advisor Product Development, Senior Advisor Process Optimization

2004 – 2006      Academic Research: Senior Research Fellow

2000 – 2004      Medical Device Development: Project Manager

1998 – 2000      Academic Research: Research Fellow

1998              PhD, Bioengineering

1991              MSc, Bioengineering

1986              BSc, Biological Sciences

## Affiliations and Qualifications

Member of DIN/ISO Expert Technical Committee 198  
Various professional qualifications related to pharmaceutical manufacturing and quality  
management

## Papers (selected)

Invited chapters in academic books (4)  
Papers in peer-reviewed journals (34)  
Numerous invited lectures and published congress abstracts

- (1) **Smith M D**, Brune J C, Wildemann B & Pruss A (2013) Whither Advanced Therapy Medicinal Products? *Transfus Med Hemoth* 40, 449–452.
- (2) Brune J C *et al.* (2012) CT Lesion Model-Based Structural Allografts: Custom Fabrication and Clinical Experience. *Transfus Med Hemoth* 39, 395–404.
- (3) Rössner E *et al.* (2011) Epiflex® A new decellularised human skin tissue transplant: manufacture and properties. *Cell Tissue Bank* 12, 209–217.
- (4) Hoburg A T *et al.* (2010) Effect of Electron Beam Irradiation on Biomechanical Properties of Patellar Tendon Allografts in Anterior Cruciate Ligament Reconstruction. *Am J Sports Medicine* 38, 1134–1140.
- (5) Scheffler S *et al.* (2007) No influence of collagenous proteins of Achilles tendon, skin and cartilage on the virus-inactivating efficacy of peracetic acid–ethanol. *Biologicals* 35, 355–359.
- (6) **Smith M D** & Mahiout A (2002) In vitro performance characteristics of a high-flux hemodialyzer with a novel polyester-polymer-alloy (PEPA) membrane. *Perfusion* 17, 41–45.
- (7) Hay P D, Veitch A R, **Smith M D**, Cousins R B & Gaylor J D S (2000) Oxygen Transfer in a Diffusion-Limited Hollow Fiber Bioartificial Liver. *Artif Organs* 24, 278–288.
- (8) Busse B, **Smith M D** & Gerlach J (1999) Treatment of acute liver failure: hybrid liver support. *Langenbeck's Archives Surg* 384, 588–599.
- (9) **Smith M D**, Smirthwaite A D, Cairns D E, Cousins R B & Gaylor J D (1996) Techniques for Measurement of Oxygen Consumption Rates of Hepatocytes during Attachment and Post-Attachment. *Int J Artif Organs* 19, 36–44.
- (10) **Smith M D**, Grant M H, Blass C R, Courtney J M & Barbenel J C. (1996) Poly(vinyl chloride) formulations: Acute toxicity to cultured human cell lines. *J Biomaterials Sci Polym Ed* 7, 453–459.
- (11) **Smith M D**, Shearer M G, Srivastava S, Scott R & Courtney J M (1992) Quantitative evaluation of the growth of established cell lines on the surface of collagen, collagen composite and reconstituted basement membrane. *Urol Res* 20, 285–288.
- (12) **Smith M D**, Barbenel J C, Courtney J M & Grant M H (1992) Novel Quantitative Methods for the Determination of Biomaterial Cytotoxicity. *Int J Artif Organs* 15, 191–194.