Contents

Contributors ix

Preface xiii

List of Abbreviations xv

1 The Development of Animal Cell Products: History and Overview 1
B Griffiths

FUNDAMENTAL ELEMENTS OF CELL GROWTH MEDIA 15

2 Water Purity and Regulations 17
P Whitehead

3 Development and Optimization of Serum-free and Protein-free Media 29
D Jayme

4 Understanding Animal Sera: Considerations for Use in the Production of Biological Therapeutics 45
R Festen

CELL ENGINEERING FOR RECOMBINANT PRODUCTS 59

5 Expression of Recombinant Biomedical Products from Continuous Mammalian Cell Lines 61
SA Jeffs

6 Production of Recombinant Viral Vaccine Antigens 79
SA Jeffs

7 A Brief Overview of the Baculovirus Expression System in Insect and Mammalian Cells 101
C Mannix

8 Stability: Establishing Clones, Genetic Monitoring and Biological Performance 113
L Barnes

9 Gene Transfer Vectors for Clinical Applications 125
A Meager

COPYRIGHTED MATERIAL

TECHNOLOGY AND FACILITIES FOR CELL CULTURE SCALE-UP **143**

10 Systems for Cell Culture Scale-up **145**
J Davis

11 Process Development and Design **173**
DK Robinson and L Chu

12 Facility Design for Cell Culture Biopharmaceuticals **187**
S Vranch

13 Monitoring, Control and Automation in Upstream Processing **203**
TS Stoll and P Grabarek

14 Services and Associated Equipment for Upstream Processing **245**
TS Stoll

15 System and Process Validation **285**
N Chesterton

PROCESSING AND PRESERVATION OF CELLS AND PRODUCTS **303**

16 Cell Harvesting **305**
P Hill and J Bender

17 Protein Concentration **331**
J Bender

18 Purification Methods **347**
M Wilson

19 Virus Safety of Cell-derived Biological Products **371**
PL Roberts

20 Formulation and Freeze Drying for Lyophilized Biological Medicines **393**
P Matejtschuk and P Phillips

21 Cell Preservation **417**
R Fleck and B Fuller

PROPERTIES OF CELL PRODUCTS **433**

22 Product Characterization from Gene to Therapeutic Product **435**
K Baker, S Flatman and J Birch

23 Protein Analysis **443**
K Baker and S Flatman

24 Glycosylation of Medicinal Products **479**
E Tarelli

25 Immunogenicity of Impurities in Cell-Derived Vaccines **491**
M Duchene, J Descamps and I Pierard

26 Potency and Safety Assessment of Vaccines and Antitoxins: Use of Cell-based Assays **497**
D Sesardic

27 Product Stability and Accelerated Degradation Studies **503**
P Matejtschuk and P Phillips

CELLS AS PRODUCTS **523**

28 Cell Culture in Tissue Engineering **525**
TE Hardingham, CM Kielty, AE Canfield, SR Tew, SG Ball, NJ Turner and KE Ratcliffe

29 The Use of Stem Cells in Cell Therapy **543**
F Martín, J Jones, P Vaca, G Berná and B Soria

30 Cells as Vaccines **559**
AG Dalgleish and MA Whelan

RISK ASSESSMENT AND REGULATORY ASPECTS **567**

31 Risk Assessment of Cell Culture Procedures **569**
G Stacey

32 Standardization of Cell Culture Procedures **589**
G Stacey

33 Good Laboratory Practice for Cell Culture Processing **603**
B Orton

34 Good Manufacturing Practice for Cell Culture Processing **613**
A Green, G Sharpe

35 International Regulatory Framework **621**
R Guenther

36 New Areas: Cell Therapy and Tissue Engineering Products – Technical, Legal and Regulatory Considerations **637**
L Tsang

Index **651**