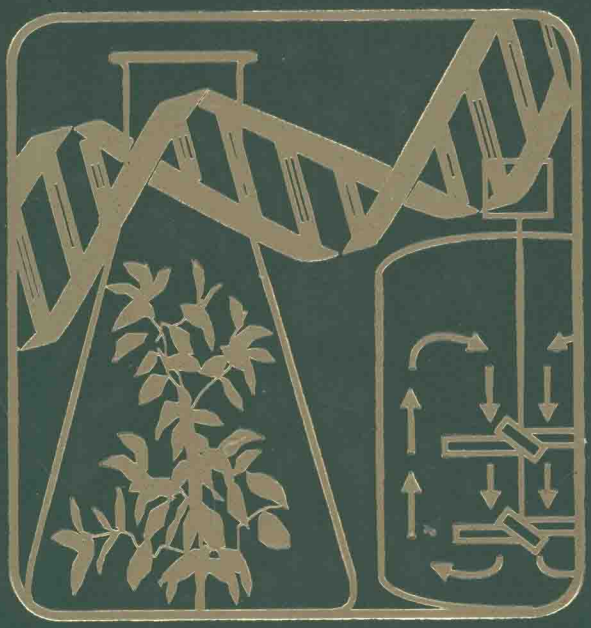
VOLUME 3

ENCYCLOPEDIA OF INDUSTRIAL BIOTECHNOLOGY



BIOPROCESS, BIOSEPARATION, AND CELL TECHNOLOGY

MICHAEL C. FLICKINGER, EDITOR

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VOLUME 3

EDITED BY

Michael C. Flickinger
Golden LEAF Biomanufacturing Training and Education Center (BTEC),
North Carolina State University,
Raleigh, North Carolina

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This work would not be possible without the patience of my family, and is dedicated to all of my students and colleagues in industrial biotechnology who contributed their knowledge and advice over the past 30 years. In particular, John Garver, David Perlman, Marvin Johnson, Henry Peppler, Richard Hanson, George Tsao, Doraiswami Ramkrishna, Richard White, Arnold Frederickson, Ken Valentas, and David Ollis have all inspired my life-long passion for exploring what microorganisms can do. I am deeply indebted to my Managing Editor Arza Seidel at John Wiley & Sons and to Sherry Wasserman, who maintained their faith in my completing this project in spite of a career transition. Without their constant effort, this work would not have been possible.

PREFACE

Advances in biotechnology, novel materials, and advanced engineering approaches continue to be translated into industrial bioprocesses, bringing new products to market at a pace significantly faster than in most other industries. Biotechnology is revolutionizing medicine, environmental monitoring and remediation, consumer products, food production, agriculture, and forestry. These applications are all the result of biotechnology on an industrial scale. This *Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology* (*EIB*) is a unique resource representing over 30 years of evolution of biotechnology techniques, which are the foundation for the biomanufacturing industry.

The *EIB* is a global compilation of knowledge from the many disciplines used in industrial practice. Contributions are included from 693 authors from 37 countries, many of whom are practicing industry or regulatory professionals. Contributions include methods for gene and protein engineering, plant biology, cell biology, the genetics of industrially used microorganisms, cell lines, development of transgenic plants, and engineered enzymes. In addition, methods are included for biochemical reactor engineering, manufacture of novel nanostructured biomaterials, bioseparation, guides for biosafety, and regulatory compliance. The genomes of over 1,000 organisms have now been sequenced and examples are included of how genomic data is used in strain engineering and identification. One third of the contributions cover GMP biopharmaceutical manufacturing, use of disposables in bioprocessing, regulatory guides, novel bioreactors, protein stability and formulation, novel separations, and nanostructured biomaterials.

Prior to the advent of recombinant DNA and monoclonal antibody technologies, the literature of industrial microbiology, tissue culture (later known as cell culture), bioseparation, and biochemical engineering were rarely combined. Examples are *Materials and Methods in Fermentation* by Solomons (Academic Press, 1969) and *Biochemical Reactors* by Atkinson (Pion Limited, 1974). The combination of biology, molecular biology, genetics, engineering, and product-focused industrial information into a single work can be traced to *Biochemical Engineering* by Aiba, Humphrey, and Millis (Academic Press, 1964, second edition 1973), followed by *Microbial Technology* by Peppler (Reinhold, 1967) and its expanded second edition by Peppler and Perlman (Academic Press, 1979). In 1975 Pirt published his very useful *Principles of Microbe and Cell Cultivation* (John Wiley & Sons), followed by the classic *Fermentation and Enzyme Technology* by Wang, Cooney, Demain, Dunnill, Humphrey, and Lilly (John Wiley, 1979). Perlman suggested that more microbiology be included in engineering texts, which led to the classic text *Biochemical Engineering* by Bailey and Ollis (McGraw-Hill, 1977, second edition 1986). This latter edition included microbe and cell biology, enzyme kinetics, metabolic stoichiometry, energetics, and molecular genetics as parts of an engineering text. In the last 15 years many useful cross-disciplinary biochemical engineering texts have been published that include biology. Bioprocess engineers now receive formal training in biology, molecular biology, and genetics. Biology also has moved toward quantitative approaches more common in engineering such as modeling of cell populations, simulation of metabolic pathways as reaction networks, quantitative genetics, mathematical descriptions of living cells as "omics," and bioinformatics methods to design and predict the properties of new enzymes, pathways, cells, and tissues.

Since the late 1980s, the cross-disciplinary information needed by industry to train new scientists, engineers, and business leaders to commercialize biotechnology has exploded. Professionals entering this industry had to assimilate fundamental and process-focused information from a wide range of biological and engineering literature, patents, monographs, short courses, and government regulatory documents. One efficient introduction to this vast knowledge was the Wiley Biotechnology Encyclopedias comprising the *Encyclopedia of Molecular Biology and Medicine;* the *Encyclopedia of Bioprocess Technology: Fermentation, Biocatalysis and Bioseparation;* the *Encyclopedia of Cell Technology;* and the *Encyclopedia of Ethical, Legal, and Policy Issues in Biotechnology* (Wiley-Interscience, 1999, available online 2003). These works organized broadly useful information in an A-to-Z format with easily searchable key words. Selected contributions from the *Encyclopedia of Bioprocess Technology* and the *Encyclopedia of Cell Technology* are included in the *EIB*. With its significantly expanded scope, the *EIB* will be useful to legal, intellectual property, environmental, education, engineering, materials science, and government regulatory and policy professionals as a guide to current industrial practice as well as the primary literature.

The future growth of biotechnology as an industry for the benefit of humanity and sustaining our environment depends upon rapid access to biology and engineering knowledge, professionals trained in multiple disciplines, and the willingness to maintain an industry-standard source of high-quality information. To be of benefit to industry, the *EIB* must be continually updated by subject matter experts to ensure that the content stays current with the rapid pace of new knowledge applied to biomanufacturing processes.

An important cautionary note—application of knowledge requires responsibility. To the vast majority of people, the extraordinary advances in biotechnology are only observed when this knowledge is used to produce commercial products. For this reason, industrialization of biotechnology carries enormous ethical, social, and environmental responsibilities. Numerous sections of the *EIB* address these critical ethical issues.

M. C. FLICKINGER

CONTRIBUTORS

Muhammad Aasim, Downstream Bioprocessing Laboratory, School of Engineering and Science, Jacobs University, Bremen, Germany, *Expanded Bed Chromatography, Surface Energetics of Biomass Deposition*

P. Marlene Absher, University of Vermont, College of Medicine, Colchester, Vermont, *Enrichment and Isolation Techniques for Animal Cell Types*

Luis A. Actis, Miami University, Oxford, Ohio, *Plasmid DNA Replication*

Myriam Adam, Laboratory of Cellular Biotechnology, Institute of Bioengineering, Faculty of Life Sciences, École Polytechnique Fédérale de Lausanne (EPFL), CH-1015 Lausanne, Switzerland, *Transient Gene Expression in Mammalian Cells*

Michael Adams, University of Georgia, Athens, Georgia, *Enzymes, Extremely Thermophilic*

S. Robert Adamson, Genetics Institute, Andover, Massachusetts, *Cell Stability, Animal*

Patrick von Aderkas, Graduate Centre for Forest Biology, University of Victoria, Victoria, Canada, *Conifers, Culture and Genetic Engineering*

Wolfgang Aehle, Genencor, A Danisco Division, Palo Alto, California; Brain Ag, Corporate Development, Zwingenberg, Germany, *Proteolytic Cleavage, Reaction Mechanisms*

Oscar Aguilar, Centro de Biotecnología Tecnológico de Monterrey, Monterrey, Mexico, *Expanded Bed Chromatography, Surface Energetics of Biomass Deposition*

Mattias Ahnfelt, GE Healthcare Bio-Sciences AB, Uppsala, Sweden, *High-Throughput Technologies in Bioprocess Development*

Kazuo Aisaka, Kyowa Hakko Kogyo Co., Ltd., Tokyo, Japan, *Cholesterol Oxidase*

Hiroyuki Akatsuka, Tanabe Seiyaku Co., Ltd., Osaka, Japan, *Diltiazem Synthesis*

Mohamed Al-Rubeai, University College Dublin, Belfield, Dublin, Ireland, *Apoptosis; Cell Cycle, Importance in Bioprocesses; Cell Cycle Synchronization*

Andrés-Rafael Alcántara, Facultad de Farmacia, Universidad Complutense, Madrid, Spain, *Enzyme-Catalyzed Synthesis of Nonnatural or Modified Nucleosides*

Marcos Almendros, Servicio de Biotransformaciones Industriales, Parque Científico de Madrid, Madrid, Spain, *Enzyme-Catalyzed Synthesis of Nonnatural or Modified Nucleosides*

Arie Altman, Robert H. Smith Institute of Plant Sciences and Genetics in Agriculture, The Hebrew University of Jerusalem, Rehovot, Israel, *Micropropagation of Plants*

Subbiah Alwarappan, Nanobioengineering and Bioelectronics Lab, Florida International University, Miami, Florida, *Nanomaterials Incorporated Bioelectronics*

Teruo Amachi, Kyoto University, Kyoto, Japan, *β-Galactosidase*

Ashraf Amanullah, Oceanside Process Research & Development, Genentech. Inc, Oceanside, California, *Animal Cell Culture Media*

Makhlouf Amoura, UPMC Univ Paris 6, CNRS and Collège de France, Chimie de la Matière Condensée de Paris, Paris, France, *Biocers, Industrial Applications*

Akinori Ando, Graduate School of Agriculture, Kyoto University, Kyoto, Japan, *Oils, Microbial Production*

Silvana Andreescu, Clarkson University, Potsdam, New York, *Biosensors, Toxicity Monitoring*

Giuseppina Andreotti, Istituto di Chimica Biomolecolare, Consiglio Nazionale delle Ricerche, Pozzuoli, Napoli, Italy, *Enzymatic Transglycosylation*

Graham Andrews, MMBD Consulting, Gresham, Oregon, *Bioreactors, Gas Treatment*

P. Anthony, University of Nottingham, School of Biosciences, Sutton Bonington Campus, Loughborough, United Kingdom, *Plant Protoplasts*

Fabienne Anton, Institut für Technische Chemie, Gottfried Wilhelm Leibniz Universität Hannover, Hannover, Germany, *Fluorescence Techniques for Bioprocess Monitoring*

William Apel, Idaho National Engineering and Environmental Laboratory, Idaho Falls, Idaho, *Bioreactors, Gas Treatment*

Hazel Aranha, GAEA Resources Inc., Northport, New York, *Virus Retentive Filters*

Claude Artois, SmithKline Beecham Biologicals, Rixensart, Belgium, *Current Good Manufacturing Practice (CGMP) Compliance for Production Rooms*

Alahari Arunakumari, Medarex, Inc., Bloomsbury, New Jersey, *Inoculum Expansion Methods, Recombinant Mammalian Cell Lines*

Yasuhisa Asano, Toyama Prefectural University, Toyama, Japan, *D-Aminopeptidase and Alkaline D-Peptidase; Opine Dehydrogenase, Secondary Amine Dicarboxylic Acids; Phenylalanine Dehydrogenase*

Yasuhisa Asano, Mitsubishi Chemical Co., Yokohama, Japan, *D-Malate*

Yoshiro Ashina, Nitto Chemical Industry Co., Ltd., Tokyo, Japan, *Nitrile Hydratase*

J.A. Atwood, Institute of Molecular Biosciences, Massey University, Palmerston North, New Zealand, *Biopolyester Particles: Preparation and Applications*

John G. Auniņš, Merck Research Laboratories, West Point, Pennsylvania, *Viral Vaccine Production in Cell Culture*

Hans Axelsson, Alfa Laval AB, Tumba, Sweden, *Cell Separation, Centrifugation*

Diana C. S. Azevedo, Federal University of Ceará, Fortaleza-CE, Brazil, *Adsorption in Simulated Moving Beds*

Heino Büntemeyer, Institute of Cell Culture Technology, University of Bielefeld, Bielefeld, Germany, *Off-Line Analysis in Animal Cell Culture*

P. K. Bachmann, Philips Research Laboratories, Aachen, Germany, *Luminescent Materials, Biological Applications*

Euiwon Bae, School of Mechanical Engineering, Purdue University, West Lafayette, Indiana, *Biosensors, Foodborne Pathogen Detection*

Lucia Baldi, Laboratory of Cellular Biotechnology, Institute of Bioengineering, Faculty of Life Sciences, École Polytechnique Fédérale de Lausanne (EPFL), CH-1015 Lausanne, Switzerland, *Transient Gene Expression in Mammalian Cells*

Richard H. Baltz, CognoGen Enterprises, Indianapolis, Indiana, *Mutagenesis*

A. Baradarajan, Indian Institute of Technology Madras, Chennai, India, *Dextran, Microbial Production*

H.S.C. Barbosa, Center of Chemistry, University of Minho, Campus de Gualtar, Braga, Portugal, *Plasmid Purification, Therapeutic Applications*

José Luis Barredo, R&D Biology, Antibióticos S. A., León, Spain, *Cephalosporin Production by Fungal Metabolic Engineering*

Raquel Barrena, Universitat Autònoma de Barcelona, Bellaterra (Barcelona), Spain, *Dehydrogenase*

Amaro G. Barreto Jr., Escola de Química, Universidade Federal do Rio de Janeiro, Rio de Janeiro-RJ, Brazil, *Adsorption in Simulated Moving Beds*

Amarjeet S. Bassi, University of Western Ontario, Faculty of Engineering, London, Ontario, *Biosensors, Environmental*

Carl A. Batt, Cornell University, Ithaca, New York, *Bionanofabrication of Nanostructures and Functional Materials*

Hans Becker, Phytochemie Universität des Saarlandes, Saarbrücken, Germany, *Bryophyte In vitro Cultures, Secondary Products*

Leo A. Behie, Pharmaceutical Production Research Facility (PPRF), Schulich School of Engineering, University of Calgary, Alberta, Canada, *Neural Stem Cells, Bioprocess Engineering*

Joan W. Bennett, Rutgers University, School Environmental and Biological Sciences, New Brunswick, New Jersey, *Aflatoxins*

Erica E. Benson, University of Abertay Dundee, Dundee, Scotland, United Kingdom, *Cryopreservation of Plant Cells Tissues and Organs*

I.S. Bentley, ABM Brewing and Enzymes Group/Rhone-Poulenc, Stockport, United Kingdom, *Enzymes, Starch Conversion*

Claudia Berdugo, The Ohio State University, Columbus, Ohio, *Aeration, Mixing, and Hydrodynamics, Animal Cell Bioreactors*

Sonja Berensmeier, Technische Universität München, Institute of Biochemical Engineering, Garching, Germany, *Bioseparation, Magnetic Particle Adsorbents*

Magnus Bergkvist, College of Nanoscale Science and Engineering (University at Albany), Albany, New York, *Bionanofabrication of Nanostructures and Functional Materials*

Martin Bertau, TU Bergakademie Freiberg, Freiberg, Germany, *Polysiloxanes, Biocatalytic Functionalization*

Joseph Bertolini, CSL Bioplasma, Broadmeadows, Victoria, Australia, *Protein Chromatography, Manufacturing Scale*

Lorena Betancor, Instituto de Catalisis, CSIC, Madrid, Spain, *Immobilized Enzymes*

Michael J. Betenbaugh, Johns Hopkins University, Baltimore, Maryland, *Insect Cells and Larvae, Gene Expression Systems*

Arun K. Bhunia, Molecular Food Microbiology Laboratory, Prude University, West Lafayatte, Indiana, *Biosensors, Foodborne Pathogen Detection*

Rebekka Biedendieck, Protein Science Group, University of Kent, Canterbury, Kent, United Kingdom, *Bacillus Megaterium and Other Bacilli: Industrial Applications*

Horst Bierau, Merck Serono, Protein Chemistry—Biophysical Characterization & PAT, Guidonia (Roma), Italy, *Spectral Data Comparability–Acceptance Criteria Definition by Statistical Analysis*

Alessandra Bini, Università degli Studi di Firenze, Firenze, Italy; Cranfield Health, Cranfield University, Bedfordshire, United Kingdom, *Biosensors, Aptamers (Aptasensors)*

John R. Birch, Lonza Biologics plc, Berkshire, United Kingdom, *Cell Products, Antibodies; Suspension Culture, Animal Cells*

Darcy Birse, Fast Trak Biopharma Services, GE Healthcare, Piscataway, New Jersey, *Cleaning and Sanitization in Downstream Processing*

Dina Biscotti, University of California, California, *Agricultural Biotechnology and Socioeconomic Effects*

Thomas Bley, Dresden University of Technology, Institute of Food Technology and Bioprocess Engineering, Dresden, Germany, *Flow Cytometry*

Janna K. Blum, School of Chemical and Biomolecular Engineering, Georgia Institute of Technology, Atlanta, Georgia; Parker H. Petit Institute of Bioengineering and Biosciences, Georgia Institute of Technology, Atlanta, Georgia, *Biocatalytic Synthesis of β-lactam Antibiotics*

Andreas S. Bommarius, School of Chemical and Biomolecular Engineering, Georgia Institute of

Technology, Atlanta, Georgia; Parker H. Petit Institute of Bioengineering and Biosciences, Georgia Institute of Technology, Atlanta, Georgia; School of Chemistry and Biochemistry, Georgia Institute of Technology, Atlanta, Georgia, *Biocatalytic Synthesis of β-lactam Antibiotics; Enzymes, Enolate Reductases "Old Yellow Enzyme"*

Jan M. Bonga, Natural Resources Canada, Canadian Forest Service—Atlantic Forestry Centre, Fredericton, Canada, *Conifers, Culture and Genetic Engineering*

Sonja Borchert, University of Erlangen-Nuremberg, Henkestr, Erlangen, Germany; Institute of Molecular Enzyme Technology at the Heinrich-Heine-University of Düsseldorf, Research Centre Jülich, Stetternicher Forst, Jülich, Germany, *Enzyme-Catalyzed Asymmetric Reduction of Ketones*

Uwe T. Bornscheuer, University of Greifswald, Institute of Biochemistry, Greifswald, Germany, *Lipases, Synthesis of Chiral Compounds, Aqueous and Organic Solvents; Monooxygenases, Baeyer-Villiger Applications in Organic Synthesis*

Birthe Borup, Codexis Laboratories Singapore Pte Ltd, Analytical Biochemistry, Singapore, *Chiral Alcohols by Enzymatic Preparation*

Richard Bott, Genencor, A Danisco Division, Palo Alto, California, *Proteolytic Cleavage, Reaction Mechanisms*

Eva Branda, University of Perugia, Perugia, Italy, *Basidiomycetous Yeasts for Production of Carotenoids*

Bugarski Branko, University of Belgrade, Belgrade, Republic of Serbia, *Immobilized Cells*

Jan Brazolot, University of Guelph, Guelph, Ontario, Canada, *Toxin Resistant Plants from Plant Cell Culture and Transformation*

Eggert Brekkan, GE Healthcare Bio-Sciences AB, Uppsala, Sweden, *High-Throughput Technologies in Bioprocess Development*

Phil J. Bremer, University of Otago, Dunedin, New Zealand, *Clean-in-Place (CIP)*

Richard Brettell, International Center for Agricultural Research in the Dry Areas (ICARDA), Aleppo, Syria, *Monocots, Tissue Culture*

Susan A. Brooks, School of Life Sciences, Oxford Brookes University, Oxford, United Kingdom, *Protein Glycosylation*

Kurt Brorson, Office of Biotech Products, Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, Maryland, *Quality by Design (QbD), Biopharmaceutical Manufacture; Virus Retentive Filters*

R. Buccholz, Technical University of Berlin, Berlin, Germany, *Microencapsulation*

Klaus Buchholz, Institute for Chemical Engineering, Technical University, Braunschweig and Institut für Organische Chemie, Universität Würzburg, Am Hubland, Würzburg, Germany, *Enzymatic Oligosaccharide Synthesis; History of Biotechnology*

Boyke Bunk, Institute of Microbiology, Technische Universität Braunschweig, Braunschweig, Germany, *Bacillus Megaterium and Other Bacilli: Industrial Applications*

Jeffrey Burkhardt, University of Florida, Gainesville, Florida, *Agricultural Biotechnology, Social Ethics, and Family Farms*

Thierry Burnouf, Human Protein Process Sciences, Lille, France, *Affinity Chromatography—Fractionated and DNA-Engineered Plasma Proteins*

Michael Butler, University of Manitoba, Winnipeg, Manitoba, Canada, *Energy Metabolism of Cells Used for Industrial Production; Protein Glycosylation, Methods for Determination*

Roxana Butoi, Merck Research Laboratories, Pennsylvania, *Proteins, Thermal Unfolding*

Pietro Buzzini, University of Perugia, Perugia, Italy, *Basidiomycetous Yeasts for Production of Carotenoids*

Joaquim M.S. Cabral, IBB-Institute for Biotechnology and Bioengineering, Centre for Biological and Chemical Engineering, Instituto Superior Técnico, Lisbon, Portugal, *Steroid Bioconversion*

Marco A. Cacciuttolo, Percivia LLC, Cambridge, Massachusetts, *Gene Expression, Human Cells*

F. Garcia Camacho, Universidad de Almeria, Almeria, Spain, *Bioreactors, Airlift Reactors*

J.-L. Flores Candia, GBF-Gesellschaft für Biotechnologische Forschung GmbH, Braunschweig, Germany, *Xanthan Gum*

A. Carloni, Cranfield Health, Cranfield University, Cranfield, Bedfordshire, United Kingdom, *Bioprocess Monitoring*

Magnus Carlquist, Lund University, Lund, Sweden; Center for Microbial Biotechnology, Technical University of Denmark, kgs, Lyngby, Denmark, *Bioreduction*

Graham Carpenter, Vanderbilt University School of Medicine, Nashville, Tennessee, *Cell-Surface Receptors: Structure, Activation, and Signaling*

Trent Carrier, Invitrogen, part of Life Technologies, Grand Island, New York, *High-Throughput Technologies in Bioprocess Development*

Alan C. Cassells, National University of Ireland Cork, Ireland, *Contamination Detection and Elimination in Plant Cell Culture*

Artur Cavaco-Paulo, Universidade do Minho, Braga, Portugal, *Biotransformation of Synthetic Fibers*

Jeffrey J. Chalmers, The Ohio State University, Columbus, Ohio, *Aeration, Mixing, and Hydrodynamics, Animal Cell Bioreactors*

Leslie Chan, Australian Institute for Bioengineering and Nanotechnology, The University of Queensland, Brisbane, Australia, *Baculovirus Kinetics in Insect Cell Culture*

Perng-Kuang Chang, USDA/ARS, Southern Regional Research Center, New Orleans, Louisiana, *Aflatoxins*

Timothy S. Charlebois, Genetics Institute, Andover, Massachusetts, *Cell Stability, Animal*

Marvin Charles, Lehigh University, Bethlehem, Pennsylvania, *Fermenter Design*

Peter S.J. Cheetham, Zylepsis, Ltd., Ashford, United Kingdom, *Enzymes for Flavor Production*

Aaron Chen, Oceanside Process Research & Development, Genentech. Inc, Oceanside, California, *Animal Cell Culture Media*

Guo-Qiang Chen, Tsinghua University, Beijing, China; Multidisciplinary Research Center, Shantou University, Guangdong, China, *Polyhydroxyalkanoates (PHAs): Separation, Purification and Manufacturing Methods*

Sébastien Chenuet, Institute of Bioengineering, Laboratory of Cellular Biotechnology, École Polytechnique Fédéral de Lausanne (EPFL), Lausanne, Switzerland, *Chinese Hamster Ovary Cells, Recombinant Protein Production*

Yusuf Chisti, School of Engineering, Massey University, Palmerston North, New Zealand, *Mass Transfer; Shear Sensitivity; Solid Substrate Fermentations, Enzyme Production, Food Enrichment*

John Chon, Percivia LLC, Cambridge, Massachusetts, *Gene Expression, Human Cells*

Douglas B. Chrisey, Rensselaer Polytechnic Institute, Troy, New York, *Bioprinting*

Jens Christensen, Merck & Co. Inc, Rahway, New Jersey, *Vent Gas Analysis*

David Clark, Centocor R&D Spring House, Pennsylvania, *Single-Use (SU) Systems*

Harald Claus, Institut für Mikrobiologie und Weinforschung, Johannes Gutenberg-Universität Mainz, Mainz, Germany, *Laccase*

Tim Clayton, Glaxo Wellcome, Beckenham, Kent, United Kingdom, *Immunoregulators; Viral Gene Therapy Vectors*

Thomas E. Cleveland, USDA/ARS, Southern Regional Research Center, New Orleans, Louisiana, *Aflatoxins*

James A. Coker, University of Maryland, Baltimore, Maryland, *Halophiles, Industrial Applications*

Steve Collier, Codexis Laboratories Singapore Pte Ltd, Chemical Development, Singapore, *Chiral Alcohols by Enzymatic Preparation*

Attilio Converti, University of Genoa, Genoa, Italy, *Biofilters for Air Purification*

Thibaud Coradin, UPMC Univ Paris 6, CNRS and Collège de France, Chimie de la Matière Condensée de Paris, Paris, France, *Biocers, Industrial Applications*

Athel Cornish-Bowden, Unité de Bioénergétique et Ingénierie des Protéines, Centre National de la Recherche Scientifique, Marseilles, France, *Kinetics, Enzymes*

David T. Corr, Rensselaer Polytechnic Institute, Troy, New York, *Bioprinting*

Rosalie J. Cote, Becton Dickinson Microbiology Systems, Sparks, Maryland, *Media Composition, Microbial, Laboratory Scale*

Deborah Court, University of Manitoba, Winnipeg, Manitoba, Canada, *Energy Metabolism of Cells Used for Industrial Production*

David J. Craik, The University of Queensland, Institute for Molecular Bioscience, Brisbane, Australia, *Cyclotides*

Jorge H. Crosa, Oregon Health and Sciences University, Portland, Oregon, *Plasmid DNA Replication*

Efrem Curcio, University of Calabria, Arcavacata di Rende (CS), Italy, *Protein Crystallization, Kinetics*

Wayne R. Curtis, The Pennsylvania State University, University Park, Pennsylvania, *Hairy Roots, Bioreactor Growth*

Alessandro D'Aprano, University of Rome, La Sapienza, Rome, Italy, *Conductivity*

Hans Von Döhren, Technical University Berlin, Institute of Chemistry, Berlin, Germany, *Peptides*

Heike Dörnenburg, University of Erlangen-Nuremberg, Institute of Bioprocess Engineering, Erlangen, Germany, *Cyclotides*

Stefan Dübel, Technische Universität Braunschweig, Institute of Biochemistry and Biotechnology, Spielmannstr, Braunschweig, Germany, *Antibody Production: Human, Recombinant*

Peter Dürre, Institut für Mikrobiologie und Biotechnologie, Universität Ulm, Ulm, Germany, *Clostridium*

Paul A. Dalby, University College London, London, United Kingdom, *Transketolases*

Tracy R. Daniels, University of California at Los Angeles, Los Angeles, California, *Monoclonal Antibodies, Human, Engineered*

Priya Dassarma, University of Maryland, Baltimore, Maryland, *Halophiles, Industrial Applications*

Shiladitya Dassarma, University of Maryland, Baltimore, Maryland, *Halophiles, Industrial Applications*

Thomas Daussmann, Codexis Laboratories Singapore Pte Ltd, Chemical Development, Singapore, *Chiral Alcohols by Enzymatic Preparation*

M.R. Davey, University of Nottingham, School of Biosciences, Sutton Bonington Campus, Loughborough, United Kingdom, *Plant Protoplasts*

John M. Davis, School of Life Sciences, University of Hertfordshire, Hatfield, Hertfordshire, United Kingdom, *Aseptic Techniques in Cell Culture*

Andria L. Deaguero, School of Chemical and Biomolecular Engineering, Georgia Institute of Technology, Atlanta, Georgia; Parker H. Petit Institute of Bioengineering and Biosciences, Georgia Institute of Technology, Atlanta, Georgia, *Biocatalytic Synthesis of β-lactam Antibiotics*

W.-D. Deckwer, GBF-Gesellschaft für Biotechnologische Forschung GmbH, Braunschweig, Germany, *Xanthan Gum*

Frank Delvigne, Fond de la Recherche Scientifique (FRNS-FRS), Bruxelles, Belgium; Faculté Universitaire des Sciences Agronomiques, Unité de Bio-industries/CWBI, Gembloux, Belgium, *Foam Formation and Control in Bioreactors*

Arnold L. Demain, Charles A. Dana Research Institute for Scientists Emeriti (RISE), Drew University, Madison, New Jersey, *Biosynthesis of Microbial Primary Metabolites*

Brian Derby, School of Materials, Materials Science Centre, University of Manchester, United Kingdom, *Bioprinting, Inkjet Deposition*

Jean Didelez, SmithKline Beecham Biologicals, Rixensart, Belgium, *Current Good Manufacturing Practice (cGMP) Compliance for Production Rooms*

C.P. Dillon, C.P. Dillon & Associates, Hurricane, West Virginia, *Stainless Steels*

Dennis Dobie, Fluor Daniel, Marlton, New Jersey, *Heating, Ventilation, and Air Conditioning*

Ed Domanico, Tri-Clover, Valencia, California, *Pumps, Industrial*

Pauline M. Doran, Monash University, Australia, *Bioreactors, Stirred Tank for Plant Cells Culture*

Barbara Doyle-Prestwich, National University of Ireland Cork, Ireland, *Contamination Detection and Elimination in Plant Cell Culture*

Denis Drapeau, Genetics Institute, Andover, Massachusetts, *Cell Stability, Animal*

Hans G. Drexler, DSMZ-German Collection of Microorganisms and Cell Cultures, Braunschweig, Germany, *Mycoplasma Contamination of Cell Cultures*

Enrico Drioli, Institute on Membrane Technology, ITM-CNR, At University of Calabria, Rende, Italy, *Biocatalytic Membrane Reactors; Protein Crystallization, Kinetics*

Jason Duex, University of Colorado Denver, Aurora, Colorado, *Growth Factors: Protein Processing, Endocytosis, and Intracellular Sorting*

Dominique J. Dumet, University of Abertay Dundee, Dundee, Scotland, United Kingdom, *Cryopreservation of Plant Cells, Tissues and Organs*

Eva Maria Egelseer, Center for NanoBiotechnology, University of Natural Resources and Applied Life Sciences Vienna, Austria, *S-layers, Microbial, Biotechnological Applications*

Lothar Eggeling, Institute of Biotechnology, Juelich, Germany, *Microbial Metabolite Export*

Dieter Eibl, Zurich University of Applied Sciences, School of Life Sciences and Facility Management, Institute of Biotechnology, Wädenswil, Switzerland, *Antibody Manufacture, Disposable Systems; Culture Establishment, Plant Cell*

Regine Eibl, Zurich University of Applied Sciences, School of Life Sciences and Facility Management, Institute of Biotechnology, Wädenswil, Switzerland, *Antibody Manufacture, Disposable Systems; Culture Establishment, Plant Cell*

Lynda B.M. Ellis, Minneapolis, Minnesota, *Database Tools for Microbial Biocatalysis*

Takakazu Endo, Nitto Chemical Industry Co., Ltd., Tokyo, Japan, *Nitrile Hydratase*

Larry E. Erickson, Kansas State University, Manhattan, Kansas, *Anaerobes*

Bruno Fabiano, G.B. Bonino, University of Genoa, Genoa, Italy, *Microbiological Induced Corrosion and Inhibition*

Zhiwu Fang, Amgen Inc., Systems Informatics, Thousand Oaks, California, *Large-Scale Chromatography Columns, Modeling Flow Distribution*

Pierre Fauquembergue, Gist-brocades, Seclin Cedex, France, *Enzymes, Fruit Juice Processing*

Gao Fei, National Key Laboratory of Biochemical Engineering, Institute of Process Engineering, Chinese Academy of Sciences, Beijing, China, *Enzyme Immobilization, Biocatalyst Featured with Nanoscale Structure*

J. Ricardo Fernández-Fernández, Chemical and Bioprocess Engineering Department, Pontificia Universidad Católica de Chile, Santiago, Chile, *Solid Substrate Fermentation, Automation*

Mario Fernández-Fernández, Universidad de Talca, Talca, Región del Maule, Chile, *Solid Substrate Fermentation, Automation*

Pedro Fernandes, IBB-Institute for Biotechnology and Bioengineering, Centre for Biological and Chemical Engineering, Instituto Superior Técnico, Lisbon, Portugal, *Steroid Bioconversion*

Gloria Fernandez-Lorente, Instituto de Catalisis, CSIC, Madrid, Spain, *Immobilized Enzymes*

James T. Fleming, University of Tennessee, Center for Environmental Biotechnology, Knoxville, Tennessee, *Bioelectronics*

Patrick Florent, SmithKline Beecham Biologicals, Rixensart, Belgium, *Current Good Manufacturing Practice (cGMP) Compliance for Production Rooms*

Ian G. Fotheringham, NSC Technologies, Mount Prospect, Illinois, *Phenylalanine*

Mark Richard Fowler, Leicester School of Pharmacy, De Montfort University, Leicester, United Kingdom, *Cell Cycle in Suspension Cultured Plant Cells; Plant Cell Culture, Laboratory Techniques*

Peter Fröhlich, TU Bergakademie Freiberg, Freiberg, Germany, *Polysiloxanes, Biocatalytic Functionalization*

Matthias Franzreb, Karlsruhe Institute of Technology, Institute for Functional Interfaces, Eggenstein-Leopoldshafen, Germany, *Bioseparation, Magnetic Particle Adsorbents*

Juan Luis De La Fuente, R&D Biology, Antibióticos S. A., León, Spain, *Cephalosporin Production by Fungal Metabolic Engineering*

Daniel Y. C. Fung, Kansas State University, Manhattan, Kansas, *Anaerobes*

Renata L.A. Furlan, Institute of Biomedical Sciences, University of São Paulo, São Paulo, SP, Brazil, *Anticancer Compounds Development, Structural Modifications and Therapeutic Applications*

Pete Gagnon, Validated Biosystems, San Clemente, California, *Chromatographic Purification of Virus Particles*

Sean R. Gallagher, Motorola Phoenix Corporate Research Laboratories, Tempe, Arizona, *Electrophoresis of Proteins and Nucleic Acids*

Mallikarjunarao Ganesana, Clarkson University, Potsdam, New York, *Biosensors, Toxicity Monitoring*

F.A.P. Garcia, University of Coimbra, Coimbra, Portugal, *Cell Wall Disruption*

Felix Garcia-Ochoa, Facultad Quimicas, Universidad Complutense, Madrid, Spain, *Oxygen Transfer Rate Determination: Chemical, Physical and Biological Methods*

Maria Gavrilescu, Research Centre for Antibiotics, Iaşi, Romania, *Static Mixing in Fermentation Processes*

Martin Gawlitzek, Late Stage Cell Culture, Genentech, Inc., San Francisco, California, *Animal Cell Culture Media*

Craig J.L. Gershater, S.B. Pharmaceuticals, Harlow, Essex, England, *Inoculum Preparation*

Tom Gervais, Centocor R&D Spring House, Pennsylvania, *Single-Use (SU) Systems*

Iraj Ghazi, The Ohio State University, Columbus, Ohio, *Large-Scale Protein Purification, Self-Cleaving Aggregation Tags*

Haile Ghebremariam, Medarex, Inc., Bloomsbury, New Jersey, *Inoculum Expansion Methods, Recombinant Mammalian Cell Lines*

Robert L. Gherna, American Type Culture Collection, Rockville, Maryland, *Culture Preservation*

Maria L. Ghirardi, National Renewable Energy Laboratory, Golden, Colorado, *Algal Hydrogen Production*

Oreste Ghisalba, Ghisalba Life Sciences, Reinach, Switzerland, *Industrial Biotransformation*

Siddartha Ghose, Aston University, Birmingham, United Kingdom, *Protein Adsorption, Expanded Bed*

Carlo E. Giartosio, Merck Serono, Protein Chemistry—Biophysical Characterization & PAT, Guidonia (Roma), Italy, *Spectral Data Comparability–Acceptance Criteria Definition by Statistical Analysis*

Friedrich Giffhorn, Applied Microbiology, Saarland University, Saarbruecken, Germany, *Dehydrogenases, Electrochemical Cofactor Regeneration*

Assunta Giordano, Istituto di Chimica Biomolecolare, Consiglio Nazionale delle Ricerche, Pozzuoli, Napoli, Italy, *Enzymatic Transglycosylation*

Lidietta Giorno, Institute on Membrane Technology, ITM-CNR, At University of Calabria, Rende, Italy, *Biocatalytic Membrane Reactors*

Paolo Giudici, University of Modena and Reggio Emilia, Reggio Emilia, Italy, *Acetic Acid Bacteria, Biotechnological Applications*

Leland Glenna, Pennsylvania State University, Pennsylvania, *Agricultural Biotechnology and Socioeconomic Effects*

Guy Godeau, SmithKline Beecham Biologicals, Rixensart, Belgium, *Current Good Manufacturing Practice (cGMP) Compliance for Production Rooms*

Ruben Godoy-Silva, The Ohio State University, Columbus, Ohio; Universidad Nacional de Colombia, Bogotá, Colombia, *Aeration, Mixing, and Hydrodynamics, Animal Cell Bioreactors*

Emilio Gomez, Facultad Quimicas, Universidad Complutense, Madrid, Spain, *Oxygen Transfer Rate Determination: Chemical, Physical and Biological Methods*

Marta Goretti, University of Perugia, Perugia, Italy, *Basidiomycetous Yeasts for Production of Carotenoids*

Johnathan Gorke, BioTechnology Institute, University of Minnesota, Minnesota, *Enzyme-Catalyzed Reactions in Ionic Liquids*

Marie-F Gorwa-Grauslund, Lund University, Lund, Sweden, *Bioreduction*

Susanne Gräslund, Structural Genomics Consortium, Karolinska Institutet, Stockholm, Sweden, *Affinity Fusions, Gene Expression*

Harald Gröger, University of Erlangen-Nuremberg, Henkestr, Germany, *Enzyme-Catalyzed Asymmetric Reduction of Ketones*

K. Grage, Institute of Molecular Biosciences, Massey University, Palmerston North, New Zealand, *Biopolyester Particles: Preparation and Applications*

Catherine Grassin, Gist-brocades, Seclin Cedex, France, *Enzymes, Fruit Juice Processing*

David R. Gray, Chiron Corporation, Emeryville, California, *Bioreactor Operations*

Steven R. Gray, North Carolina State University, Raleigh, North Carolina, *Microorganisms, Extremely Thermophilic*

Thomas Graycar, Genencor, A Danisco Division, Palo Alto, California, *Proteolytic Cleavage, Reaction Mechanisms*

J. Bryan Griffiths, Scientific Consultancy & Publishing, Salisbury, United Kingdom, *Mammalian Cell Culture Reactors, Scale-Up*

Emilio Molina Grima, University of Almería, Almería, Spain, *Microalgae, Mass Culture Methods*

M. Michael Gromiha, Computational Biology Research Center (CBRC), National Institute of Advanced Industrial Science and Technology (AIST), Tokyo, Japan, *Temperature-Dependent Molecular Adaptations, Microbial Proteins*

Tingyue Gu, Ohio University, Athens, Ohio, *Chromatography, Radial Flow*

S. Guillouet, Massachusetts Institute of Technology, Cambridge, Massachusetts, *Corynebacteria, Brevibacteria*

Jose M. Guisan, Instituto de Catalisis, CSIC, Madrid, Spain, *Immobilized Enzymes*

Maria Gullo, University of Modena and Reggio Emilia, Reggio Emilia, Italy, *Acetic Acid Bacteria, Biotechnological Applications*

David L. Hacker, Institute of Bioengineering, Laboratory of Cellular Biotechnology, École Polytechnique Fédéral de Lausanne (EPFL), Lausanne, Switzerland, *Chinese Hamster Ovary Cells, Recombinant Protein Production; Transient Gene Expression in Mammalian Cells*

Mélanie Hall, School of Chemical and Biomolecular Engineering; Parker H. Petit Institute of Bioengineering and Biosciences, *Enzymes, Enolate Reductases "Old Yellow Enzyme"*

Martin Hammarström, Structural Genomics Consortium, Karolinska Institutet, Stockholm, Sweden, *Affinity Fusions, Gene Expression*

William Hannah, Michigan State University—Philosophy, Michigan, *Agricultural Biotechnology, Food Safety, Risk, Consent, and Ethics*

Elo Harald Hansen, University of Denmark Lyngby, Denmark, *Flow Injection Analysis (FIA)*

Michael A. Hanson, Bio-Manufacturing Sciences Group, Pfizer, New York, *Biominiaturization of Bioreactors*

Satoshi Hanzawa, TOSOH Corp., Ayase-shi and Tokyo Research Laboratory, Hayakawa, Japan, *Aspartame; Thermolysin*

Colin Harbour, The University of Sydney, NSW, Australia, *Contamination Detection in Animal Cell Culture*

Keith Harding, Scottish Crop Research Institute, Dundee, Scotland, United Kingdom, *Cryopreservation of Plant Cells Tissues and Organs*

James M. Harris, North Carolina State University, Raleigh, North Carolina, *Enzymes, Extremely Thermophilic*

Scott Harrison, Genetics Institute, Andover, Massachusetts, *Cell Stability, Animal*

Martin Hartmann, University of Augsburg, Augsburg, Germany, *Immobilization of Proteins and Enzymes, Mesoporous Supports*

Richard Hassett, Invitrogen, part of Life Technologies, Grand Island, New York, *High-Throughput Technologies in Bioprocess Development*

Rudolf Hausmann, Institut für Bio-und Lebensmitteltechnik, Bereich II: Technische Biologie, Universität Karlsruhe (TH), Engler-Bunte-Ring 1, Karlsruhe, Germany, *Biosurfactants, Rhaminolipid, Microbial Production*

Martin Hedström, Lund University, Lund, Sweden, *Sampling and Sample Handling for Process Control*

Joseph J. Heijnen, Delft University of Technology, Delft, The Netherlands, *Bioenergetics of Microbial Growth*

K. Heilmann, University of Potsdam, Institute of Biochemistry and Biology, Potsdam, Germany, *Animal Cell Types, Hybridoma Cells*

Eva Heldin, GE Healthcare Bio-Sciences AB, Uppsala, Sweden, *High-Throughput Technologies in Bioprocess Development*

Gustavo Helguera, University of California at Los Angeles, Los Angeles, California, *Monoclonal Antibodies, Human, Engineered*

María J. Hernáiz, Servicio de Interacciones Moleculares, Parque Científico de Madrid, Facultad de Farmacia, Universidad Complutense, Madrid, Spain, *Enzyme-Catalyzed Synthesis of Nonnatural or Modified Nucleosides*

Birgit Hickstein, Clausthal University of Technology, Institute of Chemical Process Engineering, Clausthal-Zellerfeld, Germany, *Bioseparation, Magnetic Particle Adsorbents*

Lars Hillringhaus, Institut für Organische Chemie, Universität Würzburg, Am Hubland, Würzburg, Germany, *Glycochips*

Lutz Hilterhaus, Institute of Technical Biocatalysis, Hamburg University of Technology, Hamburg, Germany, *Biotransformation, Process Optimization, Kinetics and Engineering Aspects*

E. Dan Hirleman, School of Mechanical Engineering, Purdue University, West Lafayette, Indiana, *Biosensors, Foodborne Pathogen Detection*

Yamamoto Hiroaki, Corporate R&D Center, R&D Management, Daicel Chemical Industries, Ltd, Himeji-shi, Hyogo, Japan, *Carbonyl Reductase*

Imanaka Hiroyuki, Graduate School of Natural Science and Technology, Okayama University, Okayama, Japan, *Membrane-Surface Liquid Culture, Fungi*

Richard B. Hitchman, Oxford Expression Technologies Ltd., Oxford Brookes University, United Kingdom, *Baculovirus Expression Systems*

Bernd Hitzmann, Institut für Technische Chemie, Gottfried Wilhelm Leibniz Universität Hannover, Hannover, Germany, *Fluorescence Techniques for Bioprocess Monitoring*

Timothy John Hobley, Technical University of Denmark, Systems of Biology, Lyngby, Denmark, *Bioseparation, Magnetic Particle Adsorbents*

Paul Holmes, University College Dublin, Belfield, Dublin, Ireland, *Cell Cycle Synchronization*

H.J.G. Ten Hoopen, Delft University for Technology, Delft, The Netherlands, *Bioreactors, Continuous Culture of Plant Cells; Recirculation Bioreactor in Plant Cell Culture*

Masashi Hosokawa, Faculty of Fisheries Sciences, Hokkaido University, Hokkaido, Japan, *Edible Oils, Microbial Modification Processes*

Ching T. Hou, Renewable Products Technology Research Unit, National Center for Agricultural Utilization Research, ARS, USDA, Peoria, Illinois, *Edible Oils, Microbial Modification Processes*

Wei-Shou Hu, University of Minnesota, Minneapolis, Minnesota, *Mammalian Cell Bioreactors*

Weiwei Hu, Cell Culture Development, Biogen Idec Inc., San Diego, California, *Bioreactors, Cell Culture, Commercial Production*

Erwin Huebner, University of Manitoba, Winnipeg, Manitoba, Canada, *Characterization of Cells, Microscopic*

Holger Huebner, Technical University of Berlin, Berlin, Germany, *Microencapsulation*

Werner Hummel, Institute of Molecular Enzyme Technology at the Heinrich-Heine-University of Düsseldorf, Research Centre Jülich, Stetternicher Forst, Jülich, Germany, *Enzyme-Catalyzed Asymmetric Reduction of Ketones*

H. Hummel, Philips Research Laboratories, Aachen, Germany, *Luminescent Materials, Biological Applications*

Tony Hunt, Advanced Minerals Corporation, Santa Barbara, California, *Filter Aids*

Valerie Huse, University of Maryland, Baltimore, Maryland, *Halophiles, Industrial Applications*

Sunyia Hussain, Johns Hopkins University, Baltimore, Maryland, *Insect Cells and Larvae, Gene Expression Systems*

Yasuhiro Ikenaka, Kaneka Corporation, Hyogo, Japan, *Aminohydrolases for Production of* D-*Amino Acids*

Nicola Ilk, Center for NanoBiotechnology, University of Natural Resources and Applied Life Sciences Vienna, Austria, *S-layers, Microbial, Biotechnological Applications*

W.M. Ingledew, University of Saskatchewan, Parksville, Canada; Ethanol Technology Institute, Parksville, Canada, *Ethanol Fuel Production, Yeast Processes*

Masayuki Inui, Research Institute of Innovative Technology for the Earth (RITE), Kizugawa, Kyoto, Japan, *Amino Acids, Branched Chain,* L-*Isoleucine; L-Aspartic Acid, Production Processes*

Hisao Ito, Fermentation and Biotechnology Laboratories, Ajinomoto Co., Inc., Kawasaki, Japan, *Amino Acid Production,* L-*Lysine*

Maria J. Guardia, Camino De Purchill, Puleva Biotech Department of Process Engineering, Granada, Spain, *Mammalian Cell Bioreactors*

Dieter Jahn, Institute of Microbiology, Technische Universität Braunschweig, Braunschweig, Germany, *Bacillus Megaterium and Other Bacilli: Industrial Applications*

A.C. Jahns, Institute of Molecular Biosciences, Massey University, Palmerston North, New Zealand, *Biopolyester Particles: Preparation and Applications*

Steen Weber Jensen, Novo Nordisk A/S, Bagsvaerd, Denmark, *Insulin Purification*

Toru Jojima, Research Institute of Innovative Technology for the Earth (RITE), Kizugawa, Kyoto, Japan, *Amino Acids, Branched Chain,* L-*Isoleucine*

Carl S. Jone, Merck Serono, Protein Chemistry—Biophysical Characterization & PAT, Guidonia (Roma), Italy, *Spectral Data Comparability–Acceptance Criteria Definition by Statistical Analysis*

Jeong Chan Joo, School of Chemical and Biological Engineering, Seoul National University, Seoul, Korea, *Thermostable Proteins*

Omkar Joshi, Bayer HealthCare LLC, Berkeley, California, *Adsorption, Proteins with Synthetic Materials*

T. Juestel, Philips Research Laboratories, Aachen, Germany; University of Applied Sciences Muenster, Steinfurt, Germany, *Luminescent Materials, Biological Applications*

Dirk Jung, Advanced Materials Science, Department of Physics, University of Augsburg, Augsburg, Germany, *Immobilization of Proteins and Enzymes, Mesoporous Supports*

Beth H. Junker, Bioprocess R&D, Merck Research Laboratories, Rahway, New Jersey, *Good Manufacturing Practice (GMP) and Good Industrial Large Scale Practice (GLSP); Pilot Plants, Design and Operation*

Per Kårsnäs, Institute of Biology and Chemical Engineering, Mälardalens högskola, Eskilstuna, Sweden, *Chromatography, Hydrophobic Interaction*

Christian Kaisermayer, Project Manager Cell Culture Applications & Support, GE Healthcare, Vienna, Austria, *Microcarrier Culture*

Michael S. Kallos, Pharmaceutical Production Research Facility (PPRF), Schulich School of Engineering, University of Calgary, Alberta, Canada, *Neural Stem Cells, Bioprocess Engineering*

Manohar Kalyanpur, Consultant, Bioseparations & Pharmaceutical Validation, Plaisir, France, *Membrane Separations*

Ingo Kampen, Technische Universität, Institute for Particle Technology, Braunschweig, Germany, *Cell Disruption, Microbial, Micromechanical Properties*

Shamsher S. Kanwar, H.P. University, Summer Hill, Shimla, *Lipases*

András Kapus, Toronto Hospital, Toronto, Ontario, Canada, *Membrane Structure and Transport of Small Molecules and Ions*

Selin Kara, Institute of Technical Biocatalysis, Hamburg University of Technology, Hamburg, Germany, *Enzymatic C-C Bond Formation, Asymmetric*

Levente Karaffa, Faculty of Science and Technology, University of Debrecen, Debrecen, Hungary, *Citric Acid Processes*

R.S. Karthikeyan, Indian Institute of Technology–Madras, Chennai, India, *Dextran, Microbial Production*

Michihiko Kataoka, Kyoto University, Kyoto, Japan, *Aldehyde Reductase; Lactonohydrolase; Pantothenic Acid and Related Compounds*

Takane, Katayama, Research Institute for Bioresources and Biotechnology, Ishikawa Prefectural University,

Japan, *L-DOPA, Microbial Production; Tyrosine Phenol-lyase*

Yasuo Kato, Toyama Prefectural University, Toyama, Japan, *Opine Dehydrogenase, Secondary Amine Dicarboxylic Acids*

Randal J. Kaufman, Howard Hughes Medical Institute, University of Michigan Medical Center, Ann Arbor, Michigan, *Protein Synthesis and Secretion, Animal Cells*

Takuo Kawamoto, Kyoto University, Kyoto, Japan, *Organosilicon Compounds, Enzymatic Modification*

Romas Kazlauskas, University of Minnesota, Minnesota; BioTechnology Institute, University of Minnesota, Minnesota, *Enzyme-Catalyzed Reactions in Ionic Liquids*

Nakanishi Kazuhiro, Graduate School of Natural Science and Technology, Okayama University, Okayama, Japan, *Membrane-Surface Liquid Culture, Fungi*

Robert M. Kelly, North Carolina State University, Raleigh, North Carolina, *Enzymes, Extremely Thermophilic; Microorganisms, Extremely Thermophilic*

Christian Kennes, Chemical Engineering Laboratory, Faculty of Sciences, University of La Coruña, La Coruña, Spain, *Biofilters for Air Purification*

Mansoor A. Khan, Office of Pharmaceutical Science, Center for Drug Evaluation and Research, United States Food and Drug Administration, *Quality by Design (QbD), Biopharmaceutical Manufacture*

Soo Hean Gary Khoo, University College Dublin, School of Chemical and Bioprocess Engineering, Belfield, Ireland, *Apoptosis*

Shun-ICHI Kidokoro, Sagami Chemical Research Center, Kanagawa, Japan, *Thermolysin*

Linda A. King, School of Life Sciences, Oxford Brookes University, United Kingdom, *Baculovirus Expression Systems*

Shukuo Kinushita, Kyowa Hakko Kogyo Co., Ltd., Tokyo, Japan, *L-Glutamic Acid Production*

Shigenobu Kishino, Graduate School of Agriculture, Kyoto University, Kyoto, Japan, *Oils, Microbial Production*

Robert Kiss, Late Stage Cell Culture, Genentech, Inc., San Francisco, California, *Animal Cell Culture Media*

Robbert Kleerebezem, Delft University of Technology, Delft, The Netherlands, *Bioenergetics of Microbial Growth*

Geert-Jan De Klerk, Wageningen Tissue Culture Center, BU Biodiversity and Breeding, AA Wageningen, The Netherlands, *Adventitious Organogenesis*

Krystyna Klimaszewska, Natural Resources Canada, Canadian Forest Service—Laurentian Forestry Centre, Quebec, Canada, *Conifers, Culture and Genetic Engineering*

Claudia Kloth, Medarex, Inc., Bloomsbury, New Jersey, *Inoculum Expansion Methods, Recombinant Mammalian Cell Lines*

George K. Knopf, The University of Western Ontario, Mechanical and Materials Engineering, London, Ontario, Canada, *Biophotoreceptor Arrays*

Arthur L. Koch, Indiana University, Bloomington, Indiana, *Microbial Growth Measurement*

Gert-Wieland Kohring, Applied Microbiology, Saarland University, Saarbruecken, Germany, *Dehydrogenases, Electrochemical Cofactor Regeneration*

Fragiskos N. Kolisis, School of Chemical Engineering, National Technical University of Athens, Athens, Greece, *Reverse Micelles, Enzymes*

Hidenobu Komeda, Toyama Prefectural University, Toyama, Japan, *D-Aminopeptidase and Alkaline D-Peptidase*

Dhinakar S. Kompala, University of Colorado, Boulder, Colorado, *Cell Growth and Protein Expression Kinetics*

Jone Koo, Korea Advanced Institute of Science and Technology, Daejon, Korea, *Osmolarity Effects, Chinese Hamster Ovary Cell Culture*

Petra Kornberger, Applied Microbiology, Saarland University, Saarbruecken, Germany, *Dehydrogenases, Electrochemical Cofactor Regeneration*

Sergey Kosourov, National Renewable Energy Laboratory, Golden, Colorado, *Algal Hydrogen Production*

Alexandros Koulouris, Intelligen Europe, Thermi, Greece, *Bioprocess Design, Computer-Aided*

Udo Kragl, Rostock University, Rostock, Germany, *Biotransformation, Process Optimization, Kinetics and Engineering Aspects*

Marina Kraußer, University of Erlangen-Nuremberg, Henkestr, Erlangen, Germany, *Enzyme-Catalyzed Asymmetric Reduction of Ketones*

Christian P. Kubicek, Vienna University of Technology, Institute of Chemical Engineering, Vienna, Austria, *Citric Acid Processes*

Maria-Regina Kula, Heinrich Heine University Düsseldorf, Jülich, Germany, *Protein Purification, Aqueous Liquid Extraction*

Hidehiko Kumagai, Research Institute for Bioresources and Biotechnology, Ishikawa Prefectural University, Japan, *Tyrosine Phenol-lyase; L-DOPA, Microbial Production*

Sandeep Kumar, Pharmaceutical Research and Development, Global Biologics, Pfizer Global Research and Development, Chesterfield, Missouri, *Temperature-Dependent Molecular Adaptations, Microbial Proteins*

Arno Kwade, Technische Universität, Institute for Particle Technology, Braunschweig, Germany, *Cell Disruption, Microbial, Micromechanical Properties*

Andreas Lübbert, Institute of Biotechnology; Centre of Bioengineering, Martin-Luther-University Halle-Wittenberg, Weinbergweg, Halle (Saale), Germany, *Gas Holdup in Bioreactors*

William B. Lacy, University of California, Davis, California, *Agricultural Biotechnology and Socioeconomic Effects*

Marcelo Fernández Lahore, Downstream Bioprocessing Laboratory, School of Engineering and Science, Jacobs University, Bremen, Germany, *Expanded Bed Chromatography, Surface Energetics of Biomass Deposition*

Philippe Lam, Pharmaceutical Development Genentech, Inc., South San Francisco, California, *Freezing, Biopharmaceutical Products*

Philippe Langella, Unité d'Ecologie et Physiologie du Système Digestif (UR910), INRA, Jouy-en-Josas, France, *Secretion of Heterologous Proteins, Gram-Positive Bacteria, Lactococcus lactis*

David Laporte, University of Minnesota, Minneapolis, *Glyoxylate Bypass of Escherichia Coli, Regulation*

Alvaro R. Lara, Universidad Autónoma Metropolitana-Cuajimalpa, *Bioreactor Scale-Down*

Per Larsen, Novo Nordisk A/S, Bagsvaerd, Denmark, *Insulin Purification*

Chung Lim Law, The University of Nottingham, Malaysia Campus, Selangor, Malaysia, *Drying of Biological Materials*

David J. Leak, College London, London, *Methylotrophs, Industrial Applications*

Jean-Paul Lecomte, Dow Corning S.A., Seneffe, Belgium, *Foam Formation and Control in Bioreactors*

Anh LeDuy, Laval University, Québec, Canada, *Pullulan, Microbial Production Methods*

Pyung Cheon Lee, Ajou University, Suwon, South Korea, *Carotenoids, Microbial Processes*

Gene Lee, Percivia LLC, Cambridge, Massachusetts, *Gene Expression, Human Cells*

Gyun Min Lee, Korea Advanced Institute of Science and Technology, Daejon, Korea, *Osmolarity Effects, Chinese Hamster Ovary Cell Culture*

Lasse Lensu, Lappeenranta University of Technology, Lappeenranta, Finland, *Biosensors, Color-Sensitive*

Mark Leonard, Genetics Institute, Andover, Massachusetts, *Cell Stability, Animal*

P.A. Lessard, Massachusetts Institute of Technology, Cambridge, Massachusetts, *Corynebacteria, Brevibacteria*

John Lewis, Crucell NV, Leiden, The Netherlands, *Gene Expression, Human Cells*

Feng Li, Oceanside Process Research & Development, Genentech. Inc, Oceanside, California, *Animal Cell Culture Media*

Jincai Li, Oceanside Process Research & Development, Genentech. Inc, Oceanside, California, *Animal Cell Culture Media*

Chen-Zhong Li, Nanobioengineering and Bioelectronics Lab, Florida International University, Miami, Florida, *Nanomaterials Incorporated Bioelectronics*

Andreas Liese, Institute of Technical Biocatalysis, Hamburg University of Technology, Hamburg, Germany, *Biotransformation, Process Optimization, Kinetics and Engineering Aspects; Enzymatic C-C Bond Formation, Asymmetric*

Yun Lin, University of Ottawa, Ottawa, Canada, *Pullulan, Microbial Production Methods*

Carsten Lindemann, Boehringer Ingelheim Pharma GmbH & Co. Biberach/ Riß, Germany, *Fluorescence Techniques for Bioprocess Monitoring*

De-Hua Liu, Tsinghua University, Beijing, China, *1,2 and 1,3 Propanediol, Microbial Production Methods*

Jinsong Liu, Product Development, Abraxis BioScience, Melrose Park, Illinois, *Freeze-Drying, Pharmaceuticals*

Jacques Livage, UPMC Univ Paris 6, CNRS and Collège de France, Chimie de la Matière Condensée de Paris, Paris, France, *Biocers, Industrial Applications*

Beth Loberant, Desert Labs, Kibbutz Yotvata, Israel, *Micropropagation of Plants*

K.C. Lowe, University of Nottingham, School of Life and Environmental Sciences, University Park, Nottingham, United Kingdom, *Plant Protoplasts*

Scott Lute, Office of Biotech Products, Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, Maryland, *Virus Retentive Filters*

Susann Müller, UFZ, Helmholtz Centre for Environmental Research, Department of Environmental Microbiology, Leipzig, Germany, *Flow Cytometry*

Suzanne Ma, University of California Los Angeles, Los Angeles, California, *Antibiotics, Polyketide*

Guang-Hui Ma, National Key Laboratory of Biochemical Engineering, Institute of Process Engineering, Chinese Academy of Sciences, Beijing, China, *Enzyme Immobilization, Biocatalyst Featured with Nanoscale Structure*

Glenn Maclsaac, Medarex, Inc., Bloomsbury, New Jersey, *Inoculum Expansion Methods, Recombinant Mammalian Cell Lines*

Pérola O. Magalhães, University of Brasília, Brasília, DF, Brazil, *Lipopolysaccharide, LPS removal, Depyrogenation*

Melissa J. Mahoney, Cornell University, Ithaca, New York, *Extracellular Matrix and Cell Adhesion*

Robert Z. Maigetter, Centocor R&D Spring House, Pennsylvania, *Single-Use (SU) Systems*

Pinching Maness, National Renewable Energy Laboratory, Golden, Colorado, *Algal Hydrogen Production*

J.C. Marcos, Center of Chemistry, University of Minho, Campus de Gualtar, Braga, Portugal, *Plasmid Purification, Therapeutic Applications*

Sonny S. Mark, University of Pennsylvania Medical Center, Pensylvania, *Bionanofabrication of Nanostructures and Functional Materials*

Julia F. Markusen, Bioprocess Research & Development, Merck Research Laboratories, Rahway, NJ, *Monoclonal Antibody Production, Cell Lines*

Robert E. Marquis, University of Rochester Medical Center, Rochester, New York, *Solute Transport, Microbial*