Scott E. Mackler
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Mr. Mackler has 35 years of industry experience including corporate management, requirements setting, project planning and basis of design development, commercialization of new products, applications for process isolation and mini-environments, construction claims arbitration, contamination control audits and foreign object and debris (FOD) troubleshooting, process FMEA's, vendor/contractor identification and qualification, RFP/RFQ preparation, project financial justification, site selection services and third party design reviews. Mr. Mackler performs industrial sales and marketing due diligence on behalf of the investment banking community and facilities evaluation and assessment on behalf of real estate development firms such as Trammel Crow.

Mr. Mackler has served as General Manager for Clestra Cleanroom in the US, and is founder and principal of Cleanroom Consulting, LLC, a firm specializing in contamination control industry services including cGMP cleanroom design and controlled environment applications, troubleshooting, assessment and corrective actions for FDA validatable critical facilities, new product introductions for the contamination control marketplace, merger and acquisition advisement, outsourcing services and industrial sales & marketing consultation including customer retention strategies. Prior to Clestra, Mr. Mackler worked for Allied Signal and Union Carbide in areas related to advanced extraction and separations technology, and he holds a BSME from Rensselaer Polytechnic Institute and the MBA degree from the University of Houston. Mr. Mackler has undergone a Single Scope Background Investigation (SSBI), a Counterintelligence Scope Polygraph (CSP) and been adjudicated for access to U.S. Government classified information with access to Sensitive Compartmented Information (SCI).

At Cleanroom Consulting, Mr. Mackler has led the basis of design (conceptual design phase) teams for projects in the life sciences (human blood products-based therapeutics and autologous cell transplant) and has acted as owner representative for a spinal nerve cell therapy center as well as being actively engaged in biotechnology projects for tissue culture applications and for the manufacture of therapeutic proteins via microbial expression systems and mammalian cell culture. Pharmaceutical clients include Schering Plough, Johnson & Johnson, Cambrex, Unigene, Merck, Sharpe & Dohme, and Guilford.

Mr. Mackler also authored a strategic marketing and product development plan (“stage/gate” process) for a revolutionary new enabling technology for ELISA (enzyme linked immunoassay) testing. Mr. Mackler has provided cleanroom compatibility testing and recommended actions to semiconductor inspection tool manufacturers. He has provided on-site consultation to cleanroom contractors performing work at DuPont (semiconductor wafer fab pilot project), Lucent (fiber optics cleanrooms) and at Balazs Labs (airborne molecular contamination laboratories) as well as for new nanofabrication facilities, precision cleaning and verification facilities, high bay assembly cleanrooms, aseptic processing suites, solid and oral dosage form manufacturing plants, and has authored Cleanroom User Requirements Specifications and Cleanroom Facility Functional Specifications for a major control systems provider. Mr. Mackler has also completed several cleanroom projects for Eastman Kodak Company and is a Certified Lean Six Sigma Green Belt.

For ITT Geospatial Systems, Mr. Mackler led a 30 person Operations / Assembly Department team specializing in Contamination Control, Electrostatics, Precision Cleaning & Verification, Thermal Vacuum Bake-out and Thermal Vacuum Test Chamber process engineering & solutions.

Mr. Mackler also provides contamination control consultation and environmental assessment - including recommended actions – to a number of biotechnology companies, medical device injection molders, photolithographic stent manufacturers, and to the world's leading manufacturer of high tech filtration products in support of their "Clean Team" facilities initiatives. Mr. Mackler has been a member of the Licensing Executives Society and serves on the Editorial Advisory Boards of A2C2, the Journal of Contamination Control, American Pharmaceutical Outsourcing, the journal dedicated to pharmaceutical and biopharmaceutical contract manufacturing, as well as Pharmaceutical Formulation & Quality.

Professional Associations
o Rochester High Tech Business Council
o Rochester Engineering Society, Inc.
o Parenteral Drug Association
o ASHRAE
o International Society of Pharmaceutical Engineers
o International Society for Cell Therapy
o Semiconductor Equipment and Materials International
o Institute of Environmental Sciences and Technology
o US-Israel Biotechnology Council
o AVS Science & Technology Society
o New York Biotechnology Association

List of Publications:

"Modular Design & Construction, Part I: Project Planning & Design, Part 2: Installation & Maintenance", BioPharm, September/October 1992

"Clinical Production Facilities; Delivery, Design, Operating & Regulatory Considerations', with Stephen W. Fitzpatrick, Ph.D., Pharmaceutical Technology, September 1995

"Current Issues in the Design of Production Facilities for Cell & Gene Therapy", Genetic Engineering News, June 1996

"Project Planning & Basis of Design for cGMP Cleanrooms, Parts 1 & 2". A2C2, The Journal of Microcontamination Detection & Control, May/June 1998

"The Surprising Advantages of Modular Cleanrooms", with Patrick Boyle, CPA. A2C2, The Journal of Microcontamination Detection & Control, November 1998

"The Case for Design/Build Cleanroom Facilities Delivery". A2C2, The Journal of Microcontamination Detection & Control, November 1999

"Barrier Isolation Technology: Facilities Update". Pharmaceutical Technology, February 2000

"Barrier Isolation Technology Can Improve Life Sciences Cleanroom Applications", American Pharmaceutical Review, November 2002

"Environmental Monitoring: A Product of your Environment", Pharmaceutical Formulation & Quality, June/July 2003

Environmental Monitoring: "Particle Counts are Easy", BioProcess International, February 2004

"Upgrading the Precision Cleaning Process", Process Cleaning Magazine, September / October 2009

"Basis Of Design For Life Science Cleanroom Facilities", Engineered Systems Magazine, April 2010

"Point of View: Facilities Cleanliness Requirements", Controlled Environments Magazine, June 2010

"Failure Modes and Effects Analysis" (for cleanrooms), Controlled Environments, January 2012

"Does Device Manufacturing Need Cleanrooms?", Medical Device Summit, February 2012