

Mike Padilla

Senior Consultant, EO

Professional Experience

Michael Padilla began his medical device involvement at Baxter Healthcare in 1991. Throughout his career, he has held various positions in the medical device industry, ranging from product development to validations to quality engineering.

Professional Activities

- Mr. Padilla is an active member at the Association for the Advancement of Medical Instrumentation (AAMI), including the AAMI Process Equivalency Task Group which developed TIR 28, *Product Adoption and Process Equivalency for Ethylene Oxide Sterilization*.
- He is a frequent presenter at Sterigenics training seminars throughout the United States.

Education

Mr. Padilla holds a Bachelor of Science in Mechanical Engineering from University of Illinois at Chicago. His areas of expertise include ethylene oxide sterilization, parametric release, cycle optimization and validation.

“My goal is to establish a rapport with the customer and gain their confidence in our ability to provide a high level of quality with any project, difficult or simple.”



SteriPro
Consulting

A Division of
Sterigenics International, Inc.

Raymond Metz, Ph.D.

Consultant, EO

Professional Experience

Raymond Metz brings a diverse background to his work developing ethylene oxide (EO) process improvements for the medical industry.

- Following postdoctoral research in diabetes at the University of Iowa, Dr. Metz began his professional career at CPC International where his core responsibilities focused on ways to use genetic engineering to improve the performance of enzymes used in food processing.
- During the same period, Dr. Metz served as a charter member of the International Food Biotechnology Committee where he concentrated on issues related to genetically modified foods.
- From 1992 until 1998, Dr. Metz conducted basic research on Hodgkin's disease and on mechanisms of cancer metastasis at Loyola University.
- Since joining Sterigenics International in 1998, he has performed over 100 studies encompassing all aspects of EO sterilization.

Education

Dr. Metz received his Ph.D. in Biological Chemistry from the University of Michigan in 1982.

Publications

Dr. Metz is the author of 12 papers in peer-reviewed books and journals.

*"I visualize the patient
who will reap
the benefits of my
efforts and I do
everything possible to
deliver the goods as
quickly as I can."*



SteriPro
Consulting

A Division of
Sterigenics International, Inc.

Bill Young

Vice President, EO Technology

Professional Experience

With over 28 years of industrial experience in the areas of manufacturing operations, product development and quality assurance, William Young brings a diverse background to his work developing ethylene oxide (EO) process improvements for the medical industry.

- Mr. Young began his career at Sterigenics International (then Griffith Micro Science) in 1991 as Plant Manager following 15 years in the OTC pharmaceutical manufacturing industry where he held roles as Microbiologist, Director of Quality, Director of Manufacturing Operations and Product Development.
- Upon joining Sterigenics, Mr. Young moved from Industrial Sterilization to leadership positions, including: Director of Laboratory Operations and Director of Consulting Services and Medical Sterilization Technology at Sterigenics Corporate.
- Most recently he has focused on the development of Sterigenics' patent pending CyclEOne™ one-day, one-chamber EO process and the expansion of Parametric Release for Corporate clients.

Professional Activities

Mr. Young has been an active participant in the Association for the Advancement of Medical Instrumentation (AAMI) and has served as the Sterigenics representative on several key AAMI committees.

- One major committee, the Industrial EO Sterilization Working Group involves participation in the review and approval process for TIR 16, Process Development; TIR 20, Parametric Release; and TIR 28, Product Adoption, as well as participating in development of the U.S. position on ISO/DIS-1 11135.
- Mr. Young has presented lectures on the topics of Process Optimization, Parametric Release, and Sterilization Modalities at MDM-West, National Plastics Exposition and the Society of Plastic Engineers, as well as for clients and various medical manufacturers.
- Additionally, he has published articles in trade journals expanding the body of literature on EO sterilization and "Speed to Market" issues.

Education

Mr. Young holds a Bachelor of Science in Biology (Microbiology concentration; Chemistry/Physics minor) from the University of Illinois-Urbana. He received a Masters of Business Administration with honors from Lake Forest Graduate School of Business, Lake Forest, Illinois.



SteriPro
Consulting

A Division of
Sterigenics International, Inc.

"It is particularly rewarding to increase the customer's knowledge base and to build an ongoing relationship between our businesses."

Zihang Zheng

*“My goal
is to do the job right
the first time...
and every time.
We love to see our
customer smile.”*

Technical Specialist, EO

Professional Experience

Zihang Zheng began his career at Sterigenics International (then Griffith Micro Science) in 1996. His areas of expertise include:

- Performance qualification and requalification
- Cycle development
- Incubation reduction time of biological indicators
- D-Value determination biological indicators
- Cycle optimization and test pack development
- Residual sterilant dissipation reduction
- Product adoption
- Relative resistance
- Aging studies

Education

Mr. Zheng holds a Masters of Science in Biology from Bridgewater State College, Bridgewater, Massachusetts.



SteriPro
Consulting

A Division of
Sterigenics International, Inc.

Zhangwu Zhu, Ph.D.

Technical Research Director

Professional Experience

Zhang Zhu brings a diverse background to his work developing ethylene oxide (EO) process improvements for the medical industry.

- From 1992 to 1997, Dr. Zhu worked as a postdoctoral research fellow at the University of Wales College of Medicine where he specialized in microwave spectroscopy and computer programming.
- Beginning in 1998, Dr. Zhu worked as an independent consultant serving the ethylene oxide (EO) sterilization industry.
- In 2003, he joined Sterigenics International, where he developed, designed and fabricated a microwave spectrometer to measure the concentration of EO and water vapor in the sterilization process used to sterilize medical devices. Dr. Zhu's invention is the only instrument to date that has the specificity required for the detection and measurement of EO and water vapor. This technology has been the key to successful parametric release processing in accordance with ISO-11135 since 1998.
- Dr. Zhu also advanced the modeling of EO sterilization gas dynamics. His program has been a key tool for studying in detail the dynamics of CycleOne™, an EO sterilization cycle with highly efficient approaches to delivering critical parameters to products during sterilization. The CycleOne process, a Sterigenics exclusive, preconditions, processes and aerates in one chamber, in just one day.

Professional Activities

- Dr. Zhu has authored many articles addressing EO sterilization for national and international scientific journals.
- In recognition of his contributions to the medical device industry, Dr. Zhu was selected as one of the "100 Notable People" featured by MD&DI magazine in June 2004.

Education

Dr. Zhu holds a Bachelor of Science in Electronic Engineering from Dalian Institute of China and a Master of Science in Electronics and Instrumentation from Harbin Industry Technology University, China. He received his Ph.D. in Gas Analytical Spectroscopy from the University of Wales, Cardiff, UK.



SteriPro
Consulting

A Division of
Sterigenics International, Inc.

"I try to have a full understanding of the customer's needs so any potential issues may be dealt with immediately... and successfully."

Tim Bollnow

“It is particularly rewarding to me when I feel we have complemented or increased the customer’s knowledge base.”

Consultant, Ethylene Oxide

Professional Experience

Mr. Bollnow began his medical device career at Sterigenics International (then Griffith Micro Science) in 1996.

- Throughout his tenure, he has held various positions in the Laboratory, including Chemist and Microbiology Supervisor of Non-sterile Testing.
- He currently works as the primary coordinator on radiation sterilization projects as well as supervising the non-sterile microbiology testing and other special projects within the laboratory.
- Mr. Bollnow is a presenter for Sterigenics at its internal seminars for customers.

Education

Mr. Bollnow holds a Bachelor of Science in Biochemistry with a specialization in Biotechnology from Michigan State University. His areas of expertise include determination of bioburden, bacterial endotoxins testing (LAL), and radiation sterilization validation.



SteriPro
Consulting

A Division of
Sterigenics International, Inc.

1500 West Thorndale Avenue □ Itasca, IL 60143 □ Tel 630.285.9121 □ Fax 630.467.0960

www.sterigenics.com