

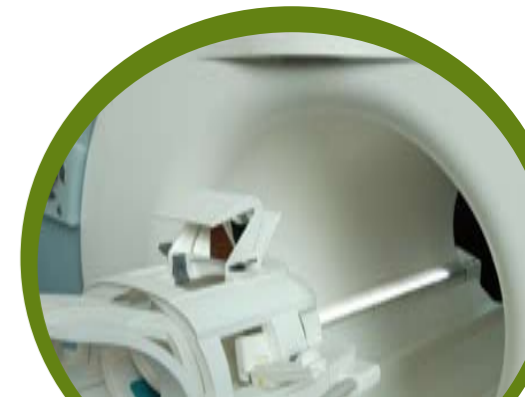


Educational programs in the Biomedical Industry:

- Pharmaceuticals
- Biologics
- Medical Devices
- Medical Centers



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Expands to the Biomedical Industry in the US

Bioforum Applied Knowledge Center is an international hub for the pharmaceutical, chemical, biotech and medical device industries as well as medical centers and the health care community. Bioforum provides an extensive range of professional learning and educational programs, expert support and consultations for the biomedical industry.

Bioforum delivers professional knowledge through:

- A broad range of short term learning programs
- Expert faculty with extensive industry experience
- On site, off site and customized courses
- Retraining and qualification of workforce

Empowering your Professional Knowledge & Skills

We seek:

- People who want to expand their knowledge and skills
- Companies who wish to leverage their organization's expertise
- Job seekers who wish to join the dynamic world of biotechnology
- **Worldwide experts to join our faculty and share their professional expertise**

You are invited to learn more about Bioforum:

www.bioforumint.com

Workforce retraining and qualification towards the biomedical industry

Clinical Trials:

Bioforum qualifies professionals from all Life Science segments: Biologists, Chemists, Pharmacists, Nurses, Physicians, Paramedics, Veterinarians, Dieticians, Medical and Paramedical staff into the world of Clinical Trials

■ **CRC - Clinical Research Coordinators**

■ **GCP - Good Clinical Practice**

■ **CRA - Clinical Research Associate**

Medical Device:

Career retraining of displaced workers, fitting their skills to the needs of the medical device industry in manufacturing, quality, regulation and more.

■ **Designated Standards (ISO 13485 on top of ISO 9000)**

■ **QSR - Quality System Regulation**

■ **Controlled Work Environment & Sterilization**





Zooming into the Biotech industry

Bioforum's educational programs are targeted at manufacturers, R&D, quality and regulatory affairs, statisticians, IT, preclinical and clinical trials professionals.

1. Closing the gap to the European Union (EU)

New opportunities to expand to the European market

SKU	Course Description	Segment	Lecturer
A10303	Marketing Authorization of Biologics in the EU	Biologics	Dr. Barbara Jentges
A10306	QP - Role, Responsibilities and Activities of the Qualified Person in the EU	Pharma / Biologics	Dr. Christopher Burgess, Mr. Richard Bonner
A10013	Technical Files – Assembling, Preparing and Writing for the EU Medical Device Directive (MDD)	Devices	Dr. Christian Jarling
A10049	Medical Device Clinical Studies & Clinical Evaluation for CE Marking According to ISO 14155:2010	Devices	Dr. Monica Tocchi

2. Regulatory Affairs (RA)

A taste of Bioforum's up to date regulatory affairs courses which cover the entire product's life cycle. Beginning with application and registration through compliance, clinical trials and up to Pharmacovigilance

SKU	Course Description	Segment	Lecturer
A10331	Pharmacovigilance - basic level	Safety	Dr. Irene Fermont
A10332	From Pharmacovigilance to Risk Management - advanced level	Safety	Dr. Irene Fermont
A10140	Development of Combination Products Regulatory & Clinical Considerations	Combination Products	Dr. Barbara Fant
A10053	Regulatory Affairs of Medical Devices	Medical Devices	Ms. Shoshana Friedman
A10017	Biocompatibility Evaluation of Medical Device & Biomaterials	Medical Devices	Dr. Shayne Gad

3. Quality

Given the importance of quality in the biotechnology industry, maintaining vigilance and continuously being up-to-date are imperatives

SKU	Course Description	Lecturer
A10029	Introduction to GMP and Quality Assurance for Manufacture and Control of Finished Pharmaceuticals	Ms. Karen Ginsbury
A10169	Writing SOPs - workshop	Ms. Karen Ginsbury
A10336	Microbiological Best Laboratory Practices	Ms. Karen Ginsbury
A10163	Environmental Monitoring	Ms. Karen Ginsbury
A10148	GDP - Good Distribution Practice	Ms. Karen Ginsbury
A10226	Technology Transfer	Dr. Malcolm Ross

4. Clinical Trials

Serving the industry, medical centers, biomedical community and CRO's, Bioforum offers a variety of learning programs in the field of clinical trials

SKU	Course Description	Lecturer
A10353	Clinical Leadership and Governance for Trial Sponsors	Dr. Monica Tocchi
A10174	Clinical Project Management	Dr. Stanley Garbus
A10014	Developing Clinical Quality Assurance (CQA) Audit Skills and Procedures	Mr. Steve Schwartz
A10248	Phase Appropriate GMP for Investigational Products	Ms. Karen Ginsbury

5. MRI Advanced Technologies

SKU	Course Description	Lecturer
A10368	MR Diagnosis & Therapy Combined Procedures Expectations & Limitations	Dr. Julian Itzcovitz

6. Validation

Bioforum's curricula for validation covers most areas of the biotech industry

SKU	Course Description	Lecturer
A10162	Cleaning Validation	Ms. Karen Ginsbury
A10039	Process Validation	Dr. Eli Schmell
A10134	Development and Validation of Bioassays	Dr. Ana Menendez
A10157	Systems and Equipment Qualification and Validation	Ms. Karen Ginsbury
A10366	Software Validation	Mr. Eyal Wulz

7. Analytical Chemistry

From the basic chromatography, to advanced courses in analytical methods development and troubleshooting

SKU	Course Description	Lecturer
A10180	Dissolution Testing	Dr. Malcolm Ross
A10318	QA at the Analytical Laboratory	Ms. Karen Ginsbury
A10246	Chiral Recognition and Separation Mechanisms	Prof. Nelu Grinberg

8. Proteins & Peptides

SKU	Course Description	Lecturer
A10177	The Analysis and Characterization of Protein Therapeutic Drugs	Mr. David Carr
A10128	Proteins & Related Materials	Prof. Ira Krull
A10007	Validation of Analytical Methods for Proteins	Prof. Ira Krull