through the integration of formulation development, GMP fill and finish services, and innovative drug delivery.

Improving the quality of human life
Biotech Formulation Leader

- Delivered over 150 formulations for more than 100 companies
- Experience with antibody, proteins, vaccines, peptides, and other innovative molecules

Partnership from R&D through Phase II

- One-stop formulation and GMP fill/finish contract services for liquid and lyophilized products
- Expertise in biopharmaceutical product and process development
- Cost effective and relevant research for efficient use of resources and materials

Innovative Delivery to Enhance Your Molecule

- LyoTip™ for prefilled delivery of lyophilized drugs
- High Concentration Formulation Technology for enhanced stability even at concentrations over 200 mg/ml
Platform Process Leverages Our Deep Experience

Our formulation development services follow a platform process based on our collective experience from more than 150 biopharmaceuticals.

Our goal is to deliver phase-appropriate optimal formulations by focusing on the most relevant formulation issues.

Experience with a wide array of innovative molecules including experience with antibodies, proteins, vaccines, peptides, and other innovative molecules.

Formulations that are Designed for Clinical and Commercial Success

**Formulation Development**

- **Preformulation**
- **Characterization**
- **Formulation development**
- **Analytical Methods development**
- **Lyo cycle development**
- **Long-term Stability Study**

Ensuring the safety and efficacy profiles of the active product candidate by stabilizing it through the manufacturing, transportation, storage, and delivery processes.

The integrity of the drug and its individual components are optimized for clinical, commercial, and regulatory needs.
State-of-the-Art GMP Facility

- 285 square feet of aseptic filling area certified Class 100 and Class 10,000 support areas
- M&O Perry Filler with a diaphragm pump
- BOC Edwards lyophilizer for batch sizes up to 4,440 units of 3 ml vials
- Getinge Steam Sterilizer and Despatch Depyrogenation System

Process Development and Drug Product Manufacturing

- Formulation including UF/DF
- Sterile filtration
- Aseptic filling of vials and prefilled syringes
- Lyophilization including cycle development and scale up

Quality Control Laboratory

- Analytical methods qualification
- Analytical method validation
- In-process and lot release testing
- GLP/GMP stability studies

GMP Fill and Finish Service

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Testing is conducted according to strict scientific protocols performed accurately, and completed on-time.

The laboratory is fully equipped with state-of-the-art instrumentation. Final product testing services include:

- Sterility
- Bioburden
- Endotoxin
- Stability
- Protein Concentration
- Moisture Analysis
- HPLC
- Capillary Electrophoresis
- Total Organic Carbon
- pH and Conductivity
- Surface Monitoring
- Particle Counting
- Lyophilization

IntegrityBio offers GMP facilities to manufacture sterile lyophilized formulations. The lyophilization facility at IntegrityBio includes a BOC Edwards lyophilizer capable of producing 4,400 3 ml vials per run.

Our production capacity is ideal for phase I and II products. In order to increase efficiency, precision, and control of the lyo process, IntegrityBio also provides lyophilization cycle development services.

Aseptic Filling

IntegrityBio's aseptic filling and capping process utilizes proven equipment and provides the most efficient control of the production fill line. The facility is validated to produce up to 10,000 vials or prefilled syringes per production lot within a class 100 environment.

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LyoTip™ Delivery System

One-step Reconstitution and Injection for Lyophilized Drugs

- Prefilled container closure system screws to a prefilled diluent syringe and needle
- Immediate reconstitution as plunger is pushed
- Spiral chamber effectively reconstitutes and simultaneously injects drug

Feasibility Studies provide Quick Evaluation of LyoTip™ Delivery System

- We offer technical feasibility studies including lyophilized formulation optimization, LyoTip™ fill and finish, and stability studies
- LyoTip™ intellectual property patents are issued and pending, and available for licensing

Ease of a Prefilled Syringe with the Stability of a Lyophilized Drug

- User friendly design favored by patients eliminates need for separate mixing steps
- Designed for use with existing fill/finish and lyophilization processes
- May permit decreased use of cold chain handling
- Cost effective, highly valued differentiation for SC and IV lyophilized drugs

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High Concentration Formulation (HCF) Technology

- Permits concentration of intravenous liquid and lyophilized biologics into liquid subcutaneous injections
- Concentrations of up to 300 mg/ml allowing 1 ml injections
- No change to molecule is required
- Proprietary Blends of Amino Acid Stabilizers allow High Protein Concentration
  - Blend is optimized for concentration, aggregation, syringeability, and stability
  - Stabilizers are non-active and FDA approved

Feasibility Studies provide Quick Evaluation of HCF Technology
- We can test your molecule in technical feasibility studies including prescreen characterization, HTS screening, and stability studies
- HCF intellectual property patent pending and available for licensing

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About Our Team

Led by founder Byeong Chang, PhD, the IntegrityBio team brings decades of combined industry experience to provide our customers with a level of confidence unparalleled in formulation development and contract manufacturing. Dr. Chang's experience spans more than 20 years including 11 years with Amgen, Inc. The collective experience of the Integrity team includes formulation of many leading biotechnology drugs including Epogen®, Aranesp®, Rebif®, Kineret®, and Luveris®.

About Our Clients

Since our inception in 2003, IntegrityBio's core business of formulation development has successfully served over 100 firm's including both early stage companies and many of the world's largest biotechnology, pharmaceutical, and medical device companies.

How Can IntegrityBio Help You?

We look forward to the opportunity of speaking with you to discuss how IntegrityBio can help you attain your company's goals.

Call (805) 445-8422 or email info@integritybio.com

"At IntegrityBio, we are committed to providing superior quality in all aspects of our operation as we strive to become your first choice for contract manufacturing.”

Byeong Chang, Ph.D.

IntegrityBio Founder and President

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