

# MILE HIGH MANUFACTURING

BY ADAM RUBENSTEIN



When one thinks of a drug manufacturing facility, a common vision is of a highly automated pharmaceutical production plant containing milling, micronizing and mixing machines that yield capsules, tablets and liquids. The production of traditional small-molecule drugs is now giving market share to the rise of biopharmaceutical products such as proteins, peptides, antibodies and their fragments. Soon these new-generation biotech products may very well yield market share to stem cell-based regenerative therapeutics. Each of these products requires unique and highly specialized manufacturing. In addition, consider the product diversity mix, diagnostic assays, the vast array of medical devices—commercial scale manufacturing may be as complex and costly an endeavor as the discovery, R&D, and clinical trial processes.

Colorado is home to manufacturers of small molecules, biopharmaceuticals, diagnostics and devices, and a few of the world's best-sell-

ing bioscience products. Specialized producers, from independent contract manufacturers to industry behemoths, and FDA-approved facilities populate the Front Range. The following list includes examples of manufacturing in Colorado.

## BIOPHARMA MANUFACTURING

**Amgen** (Longmont and Boulder, CO) a leading human therapeutics company pioneered the development of novel products based on advances in recombinant DNA and molecular biology. The Company launched the biotechnology industry's first blockbuster therapeutics, Aranesp® and Epogen®. Amgen LakeCentre facilities manufacture treatments for several conditions, including chemotherapy side effects, anemia in patients with chronic kidney disease and osteoarthritis. LakeCentre produces Kineret® (anakinra) along with palifermin and other pipeline product candidates in late-stage clinical development, while Longmont is dedicated



commercial targets. The Company is focused on addressing the challenges of historically difficult-to-manufacture peptides by using their proprietary technology to minimize toxicity during bacterial growth and reduce the chemical synthesis waste stream. By enhancing yield and simplifying downstream processing, the Biopure-Process™ reduces the overall costs of development, including both materials and purification, while accommodating the production of long, toxic and hydrophobic peptides.

**CBL** (Chemical and Biopharmaceutical Laboratories) (Boulder, CO) is a global peptide manufacturing technology company providing the industry with novel chemistries in key areas of solid phase peptide and organic synthesis. Products in the CBL catalog number in the hundreds.

#### PHARMA CONTRACT MANUFACTURING

**TOLMAR** (Fort Collins, CO) is a pharmaceutical R&D, manufacturing and commercial operation company that develops and manufactures both proprietary and generic pharmaceutical products in the dental, dermatology and oncology arenas. The Company has a wide variety of production capabilities, including creams, ointments, gels, solutions, liquids, injectables, and powder fill. Their production facilities include chemistry and microbiology laboratories, multi-shift production operation, cGMP- and EU cGMP-compliant manufacturing, liquid, semi-solid, lyophilization, and injectable filling lines as well as warehouse and cold-chain distribution capability. Tolmar has 15 approved and marketed products. Additionally, TOLMAR has three developed products are in active clinical trials, five under review at the FDA, and eight products are in the development stage. Company specializations include formulation and analytical development, primary package design and development, as well as IND, ANDA and NDA CMC support.

#### MEDICAL DEVICE MANUFACTURING

**Baxa Corporation** (Englewood, CO) was founded in 1975 with a mission to develop innovative products of superior quality for hospital pharmacies nationwide. In 2010, Baxa doubled its production cleanroom space and added assembly and warehouse space, expand-

to the manufacture of Epogen (Epoetin alfa) and Aranesp (darbepoetin alfa).

**Merck** acquired **Insmed's** (Boulder, CO) follow-on biologic candidates and their commercial manufacturing facilities. These follow-on biologic candidates include INS-19 and -20, recombinant forms of granulocyte-colony stimulating factor (G-CSF), both are currently being evaluated in Phase I trials for their ability to prevent infections in patients with cancer receiving chemotherapy, and are designed to allow for less frequent dosing.

**Roche's** (Boulder, CO) production plant plays an important role in the pharmaceutical research, development and manufacturing activities of its parent company, Roche of Basel, Switzerland. The Boulder manufacturing plant has provided R&D and manufacturing prowess to bring a variety of products to market, some of which include:

- **Fuzeon®** (enfuvirtide), the first in a new class of anti-HIV drugs known as fusion inhibitors, which prevents the HIV virus from infecting healthy T-cells. The active ingredient in Fuzeon is a 36-string amino acid peptide considered the most complex drug ever chemically synthesized at such a large scale.
- **Valcyte®** (valganciclovir) and **Cytovene®** (ganciclovir), antiviral agents prescribed to prevent and slow the spread of cytomegalovirus infection in immunocompromised individuals, including transplant recipients and people with AIDS.
- **Rocaltrol®**, used for the treatment of bone-reducing osteoporosis.

#### PEPTIDE PRODUCERS

**AmideBio** (Boulder, CO) is a biotechnology company focused on providing peptide and protein research reagents and clinical products for a diverse array of research and

ing capacity to meet customer demand and ensure on-time product shipments to customers around the world. The facility features 27,000 ft<sup>2</sup> for manufacturing with an 8,000 ft<sup>2</sup> ISO Class 8 (equivalent to a Class 100,000) cleanroom and a 30,000 ft<sup>2</sup> warehouse.

Baxa products, systems and professional services now encompass virtually every facet of compounding and dispensing fluid medications. Currently, more than 3,000 hospitals worldwide use Baxa products every day to produce more than 450,000 safe medication doses.

**Biotricity Medical** (Aurora, CO) is a medical device research and manufacturing company specializing in developing long-term power requirements for implanted devices based on bioelectric generation. The Company is currently focused on EpiVolt™, an implantable biogenerator that is able to power implanted biomedical devices including pacemakers, insulin pumps, Cochlear implants, artificial retinas and vagal nerve stimulators. The device creates electricity indefinitely and provides a long lasting power source for implanted medical devices,

designed to function for greater than 15 years of uninterrupted power.

**C5 Medical Werks** (Grand Junction, CO) serves medical manufacturers by offering state-of-the-art ceramic manufacturing, materials expertise, and custom engineering support to prototype and commercialize their designs and patents. The Company focuses on the orthopedic, dental and spine implant markets.

**CaridianBCT** (Lakewood, CO) origins date back to 1964 when founders Bob Collins and Ran Bellows established COBE Laboratories to meet emerging needs for custom heart-lung tubing packs. COBE Laboratories evolved into a market leader in the automated blood component processing technology and medical specialty products industry. In 1990, the Company was acquired by Gambro, a publicly traded, multinational health care company based in Sweden and in 2011 CaridianBCT was acquired by Terumo in 2011. The Company works to maintain its position as a leading global manufacturer and provider of products in apheresis collections, therapeutic apheresis, cell therapy systems, whole blood processing and pathogen reduction technologies.

**Covidien** (Boulder, CO) began in 1967 as Valleylab and has been a world leader in the design, manufacturing and marketing of advanced energy-based medical systems, instruments and accessories. While the Company's ongoing R&D is aimed at providing next generation solutions for an array of surgical and oncological challenges. Energy-based technologies harness electricity for surgical and other healthcare procedures such as ablation. The Covidien team works locally to develop, manufacture and market innovative interventional oncology solutions that focus primarily on ablation products.

**Mountainside Medical** (Boulder, CO) specializes in the contract manufacturing of complex, tight tolerance medical device components and instruments. The Company offers a diverse array of value-added manufacturing services with a primary core competency in high precision machining, with a specialization in laparoscopic instruments and jaws, orthopedic implants and instruments, product prototyping and pilot manufacturing.

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