

First Class in Potent Compound Safety Handling

Excella GmbH in Feucht, Germany has met the criteria established under the SafeBridge® program for "Potent Compound Safety Certification" and has been deemed competent and proficient in the safe handling of potent active pharmaceutical ingredients ("APIs") and potent drug products. Excella becomes the first company worldwide to achieve SafeBridge Potent Compound Safety Certification for the manufacture of oral solid dosage forms ("OSD").

Excella GmbH is part of FAREVA, one of the top 10 contract manufacturing organizations in the world. Excella GmbH provides Contract Manufacturing Services, especially for the development, clinical supply and commercial manufacturing of highly potent APIs and solid dosage forms containing critical actives with low occupational exposure levels. The company offers a cGMP compliant and FDA / EMEA / Anvisa certified environment and is serving more than 80 markets around the world including the US, EU and Japan.

The SafeBridge Potent Compound Safety Certification of Excella applies to specific laboratory and manufacturing areas involved in the manufacture of highly potent OSD. SafeBridge conducted a 60-element review of health and safety programs, procedures, containment and exposure control of OSD operations with occupationally potent active pharmaceutical ingredients at the company's site. Based on the quantitative results of the Potent Compound Safety Certification program, SafeBridge certifies that Excella meets current industry standards for the safe handling of potent APIs in the identified areas.

The SafeBridge® Potent Compound Safety Certification program evaluates performance with established criteria in management, compound evaluation, exposure control and communication elements of potent compound production operations. Elements of the program include on-site assessment of the potent compound manufacturing and laboratory areas and equipment, training, toxicology and industrial hygiene.

Since program inception in 1999 eleven organizations have achieved "Potent Compound Safety Certification". The Excella OSD facility joins eight other facilities actively involved in the SafeBridge® Certification program.

SAFEBRIDGE CONSULTANTS, INC. is the premier occupational health and safety consulting firm to the pharmaceutical, biotechnology and fine chemical industry with offices in Mountain View, CA, New York, NY and Liverpool, UK. SafeBridge® has provided the Potent Compound Safety Triangle™ of services in industrial hygiene, occupational toxicology and industrial hygiene analytical chemistry to over 500 business units worldwide and is a leader in recognizing, evaluating and controlling exposures to potent active pharmaceutical ingredients and products.

For more information, contact:

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