

# Cytotoxic Formulation & Filling

## Logical extension

As a global leader in the manufacture of commercial-scale sterile pharmaceuticals, a logical step for DSM was to expand this expertise by offering filling and lyophilization of cytotoxic products. Originally requested by customers and now implemented since early 2008, this represents another valuable integrated service.

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## Flexible Cytotoxic Services

- :: Flexible commercial scale services
  - :: Dedicated suite
  - :: RABS system
  - :: API storage
  - :: Key access only
- :: Complete fill and finish manufacturing
  - :: Aseptic liquid filling and lyophilization
- :: Options for expanded development and analytical services
- :: Global experience & compliance systems
- :: Flexible scheduling
- :: Flexible batch sizes
- :: Potent Compound Safety Certification from SafeBridge Consultants, Inc.
- :: Dedicated, highly experienced personnel
- :: Exceptional customer service

# Pharma Dosage Forms

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## SafeBridge Certification

In 2009, DSM's Greenville facility in North Carolina received the Potent Compound Safety Certification from SafeBridge® Consultants, Inc. This certification recognizes DSM's competency and proficiency in the safe handling of potent active pharmaceutical ingredients (APIs) and potent drug products, and applies to the site's potent sterile production area, and the associated quality control laboratories.



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SafeBridge conducted a 60-element review of programs, procedures, containment and control of the active pharmaceutical ingredients at DSM's site. This third party certification verifies performance based on established criteria in management, evaluation, containment, 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 the associated equipment, training, and toxicology and industrial hygiene support.

