

SafeBridge® Potent Compound Safety Certification and Gap Assessment Program

Separating “Contenders” from “Pretenders”

The SafeBridge Potent Compound Safety Certification program is a ‘ground breaking’ tool for drug innovators and contract manufacturing organizations (CMOs) to understand and assess capabilities for safely handling potent active pharmaceutical ingredients (APIs) and products. The Certification program and the related Gap Assessment program (which utilizes qualitative rather than quantitative scoring) have been used at numerous companies, including big pharmaceutical companies, to assess their capabilities. Contract manufacturers that have achieved SafeBridge Certification have found it to be an effective framework to protect worker health and attract potential clients to their facilities.

Certification is based on the successful implementation of the “systematic approach” to potent compound safety, including:

- ▶ “Hardware” (facility features, process equipment and engineering controls), and
- ▶ “Software” (programs, procedures and practices)

The four (4) major areas covered are:

1. Program Management
2. Hazard Evaluation
3. Containment and Controls (50% of the score)
4. Communication

During on-site assessment, our team evaluates both physical plant and equipment items (containment, process technology and ventilation systems) and assesses program items such as occupational toxicology, industrial hygiene, safety, training, medical surveillance. A company is considered Certified after an on-site assessment by two experienced and board-certified SafeBridge health professionals and achieving the minimum scoring requirements in the four major areas.

The deliverable is a written Certification or Gap Assessment report which includes findings, comments, and recommendations based on the evaluation of 60 criteria points. In the Certification process, each criterion and each of the four



major program areas are numerically graded. To receive a Letter of Certification, a minimum overall score of 65% must be achieved with none of the four program area scores under 55%. For the gap assessment, a qualitative grade scale spans the follow possible conclusions: industry leadership; meeting industry standards; needing improvement; and does not exist.

For more information on how your company can become SafeBridge Certified in potent compound safety and for a list of Certified companies, contact SafeBridge Regulatory and Life Sciences Group at allan.ader@safebridge.com or visit our website at safebridge.com

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