Question:

What can IV drug manufactures do to help prevent the loss of sterility due to compromised IV solution bag integrity during labeling?
라벨 작업 도중 IV 용액 백의 완전성 훼손 때문에 제품의 무균 상태가 상실되는 것을 방지하기 위하여 IV 의약품 제조업체가 어떻게 해야 하는가?

Answer:

The risk of loss of sterility during labeling can be reduced through the use of nonimpression printing devices for labeling. If a manufacturer uses labeling equipment to apply a label on an IV solution bag and that labeling equipment makes an impression on the IV bag, procedures should be in place to inspect the labeling equipment regularly, particularly after any maintenance is performed. Manufacturing equipment must not have any rough or sharp surfaces that will create punctures or areas of weakness in the IV solution bags. Prevention is important: damaged IV bags may elude detection by standard examinations and tests, including checks for leaks. Manufacturers are reminded that equipment maintenance and cleaning must be appropriate to prevent malfunctions or contamination that would alter the quality or purity of a drug product (see 21 CFR 211.67).
NI 인쇄 장치를 사용해 라벨 작업을 함으로써 라벨 작업 도중 무균성 상실 리스크를 줄일 수 있다. 제조업체가 라벨링 설비를 사용해 IV 용액 백의 라벨 작업을 실시하고 이 라벨링 설비가 IV 백에 임프레션을 만든다면, 정기적으로(특히 유지 관리 이후에) 라벨링 설비를 검사하는 절차를 구비한다. IV 용액 백에 구멍이나 약한 부위가 형성되게 할 수 있는 거친 표면이나 날카로운 표면이 제조 설비에 없어야 한다. 예방이 중요하다. 표준 검사나 시험(누출 점검 포함)으로 손상된 IV 백을 찾지 못할 수 있다. 의약품의 품질이나 순도에 영향을 줄 수 있는 오염이나 오작동 방지에 적절하게 설비 유지관리 및 세척을 해야 한다(21 CFR 211.67).

추가 정보(Additional information): FDA 가이드라인

- Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice
- Container Closure Systems for Packaging Human Drugs and Biologics

References:

- 21 CFR part 211: Current Good Manufacturing Practice for Finished Pharmaceuticals
- 21 CFR 211.22: Responsibilities of quality control unit
- 21 CFR 211.80: General requirements (for the control of components and containers)
- 21 CFR 211.94: Drug product containers and closures
- 21 CFR 211.67: Equipment cleaning and maintenance
- 21 CFR 211.100: Written procedures; deviations

리콜 공표(Recall announcements):

https://www.fda.gov/about-fda/website-policies/website-disclaimer

FDA WL(Warning Letters):

https://wayback.archive-it.org/7993/20161022233351/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm233010.htm

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