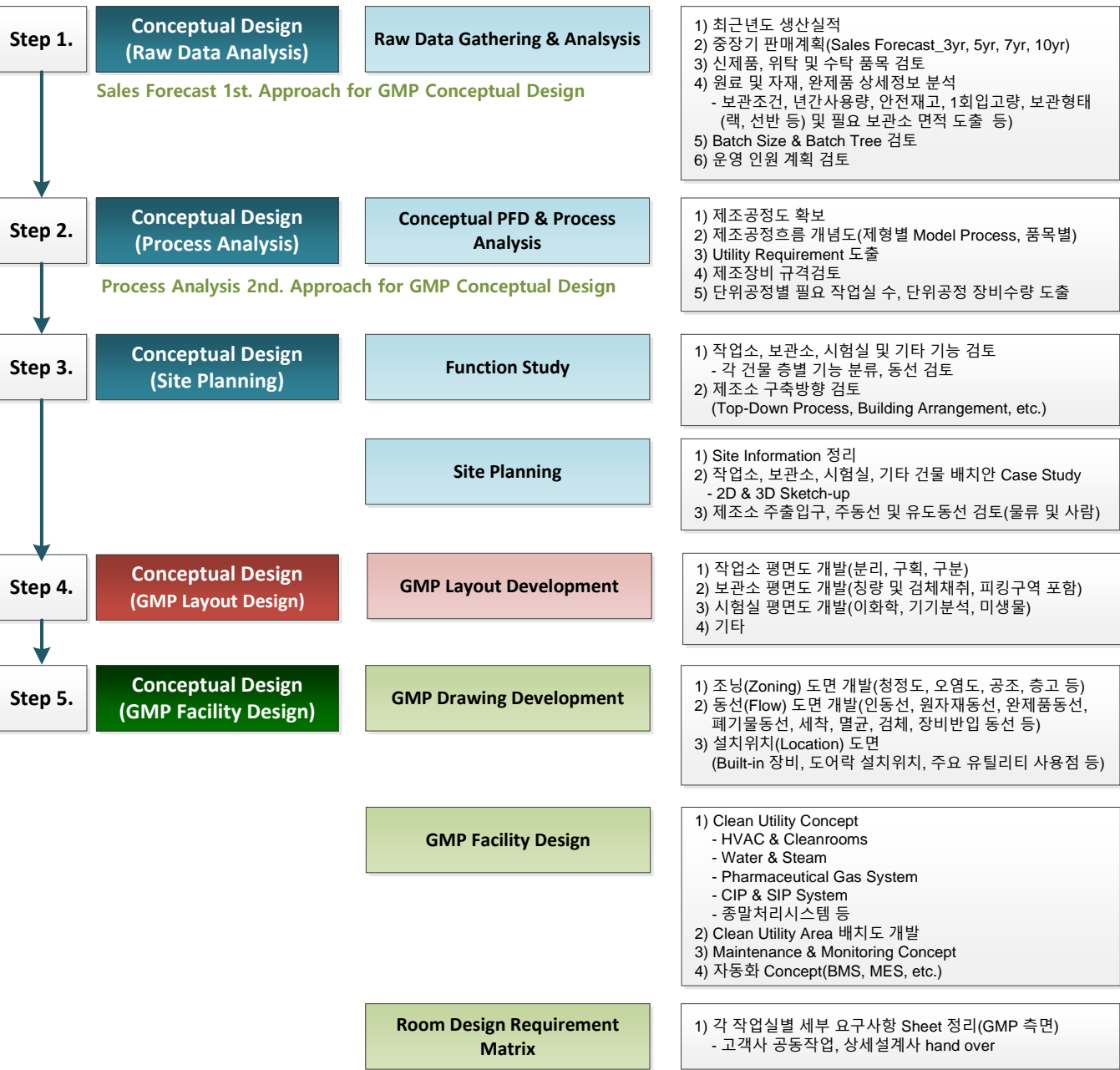
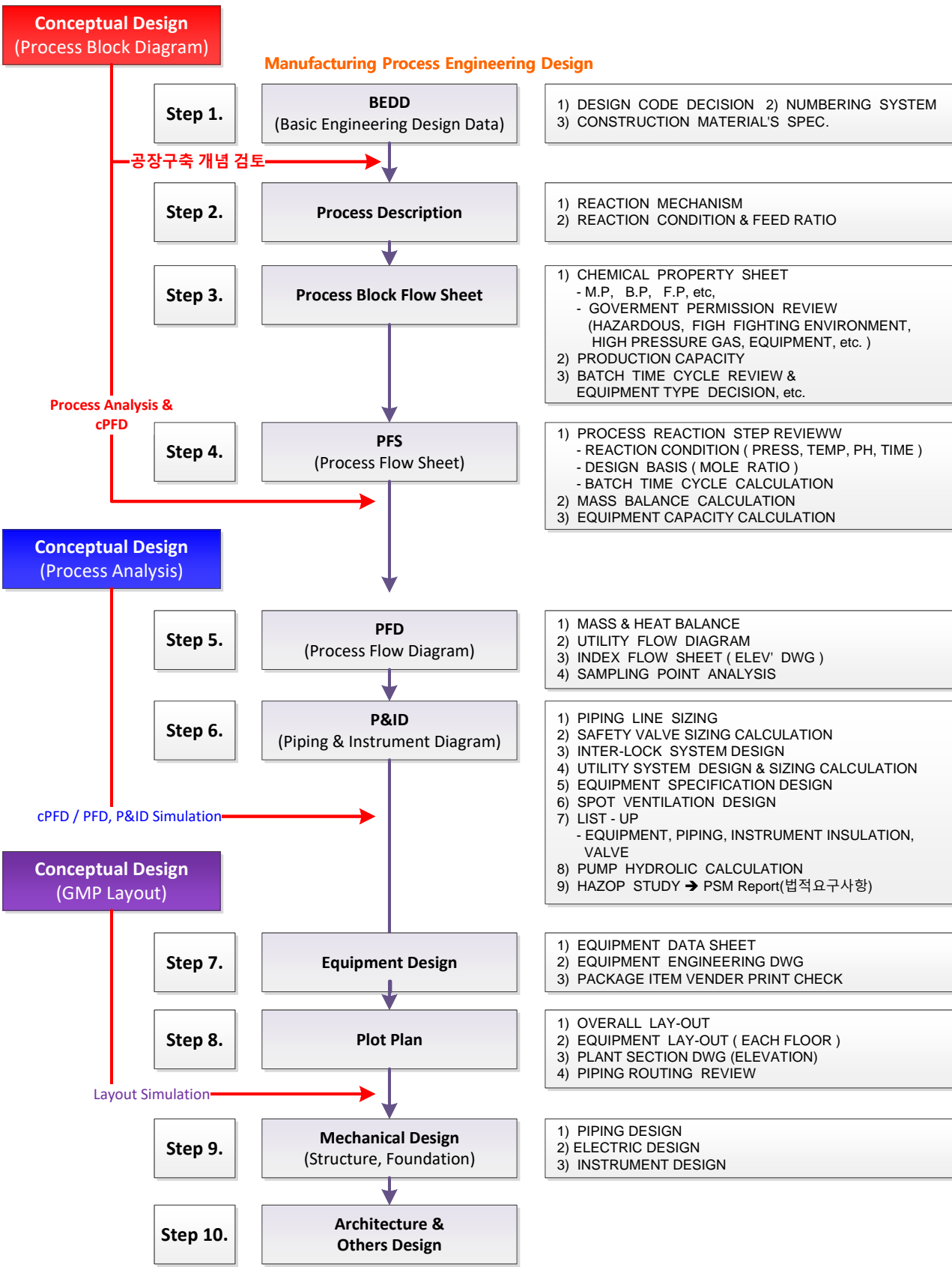


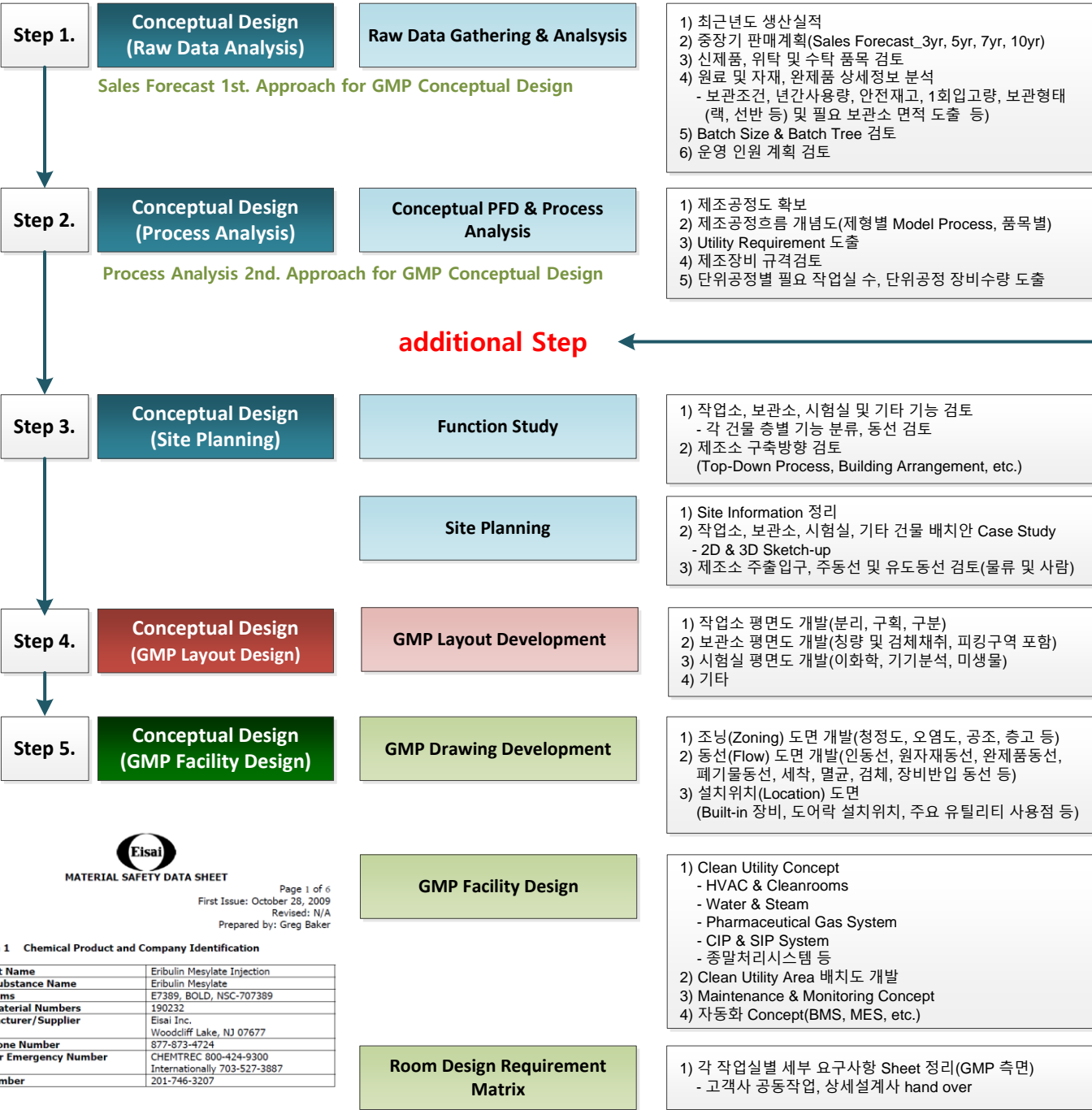
■ General(완제의약품, 기능성식품, 의료기기 등) Conceptual Design_5 Step



■ 원료의약품(합성, 발효, 추출 등) Conceptual Design_10 Step

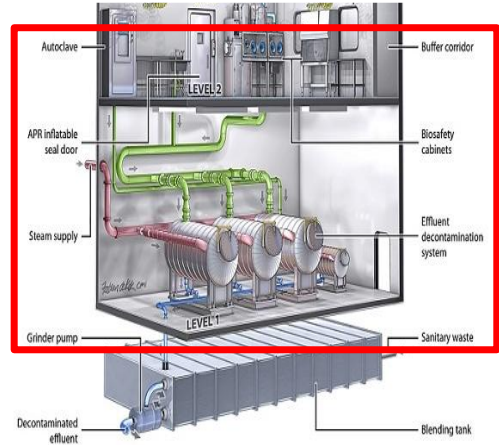
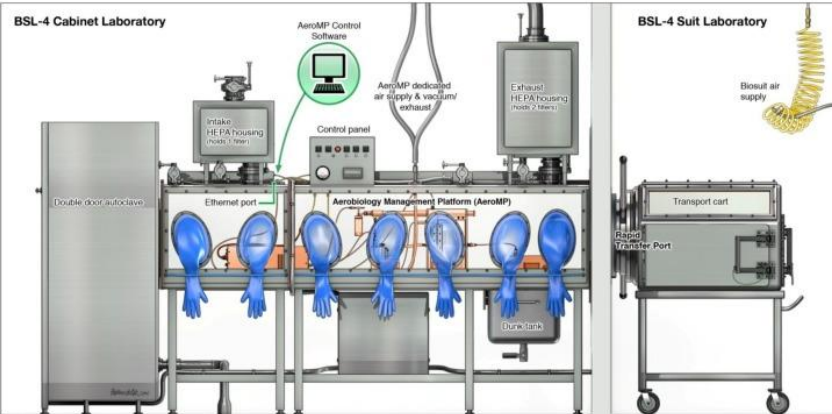


■ 특수제제(High Potent 의약품) Conceptual Design_ Additional Step



RPN Matrix			Probability of Detection					
			1	3	5	7	9	
			Very High	Moderate	Low	Remote	Very Remote	
Risk Score (SEV x OCC)	58,320	High Risk	58,320	174,960	291,600	408,240	524,880	
	45,360	Medium Risk	45,360	136,080	226,800	317,520	408,240	
	32,400	Low Risk	32,400	97,200	162,000	226,800	291,600	
	19,440	Rare Risk	19,440	58,320	97,200	136,080	174,960	
	6,480	No Risk	6,480	19,440	32,400	45,360	58,320	
226,800 < RPN ≤ 524,880			1) 작업자 보호장비 착용: 무진폭+오버가우닝 및 Powered, air-purifying respirator(PAPR)+이중 장갑+Shoes Cover 2) 단, 신체 일부만 노출될 경우(BSC 등), 무진폭+오버가우닝+N95 Mask+고글+이중 장갑+Shoes Cover 및 노출부위 전용 팔 토시 등 사용 가능					Critical priority -Planning
162,000 < RPN ≤ 226,800			무진폭+오버가우닝+ N95 Mask, 고글 및 노출부위 전용 팔 토시+이중 장갑+Shoes Cover					Critical priority
32,400 < RPN ≤ 162,000			무진폭+오버가우닝+ N95 Mask, 고글+이중 장갑+Shoes Cover					High Priority
19,440 < RPN ≤ 32,400			무진폭+오버가우닝+ N95 Mask, 고글+이중 장갑					Moderate Priority
6,480 < RPN ≤ 19,440			무진폭+ Shoes+장갑					Low Priority
단, Powder and/or Liquid Handling시 바닥에 쏟아져 파손되어 외부로 노출되었을 경우, 즉시 PAPR을 착용할 수 있도록 가까운 장소에 배치함.								

Section	Clean Class	Description of Contaminant Level	
Level 1	Level 1	오염도 매우 높음. 독성 원료 및/또는 제품 다량 노출 구역 (예: Globe Box 내부)	High Contaminant
		오염도 다소 높음. 독성 원료 및/또는 제품 소량 노출구역. (예: QC BSC 내부 검체 Open 구역, 기기분석실 BSC 내부 검체 Open 구역)	Medium Contaminant
Level 3	Level 3	오염도 보통. 독성 원료 및/또는 제품 직접 노출 없음. 독성 원료 및/또는 제품과 직접 접촉한 용기의 세척 및 불활화 구역 (예: 사용한 용기의 세척구역, 폐기를 처리구역)	Low Contaminant
Level 4	Level 4	오염도 거의 없음. 독성 원료 및/또는 제품 노출 없음. 오염도 Level 3 이하를 위한 준비구역 또는 외부세척이 완료된 완제품 이동구역	Rare Contaminant
Level 5	Level 5	오염도 전혀 없음. 독성 원료 및/또는 제품 전혀 노출 없음.	No Contaminant



Eisai MATERIAL SAFETY DATA SHEET Page 1 of 6 First Issue: October 28, 2009 Revised: N/A Prepared by: Greg Baker	
Section 1 Chemical Product and Company Identification	
Product Name	Eribulin Mesylate Injection
Drug Substance Name	Eribulin Mesylate
Synonyms	E7389, BOLD, NSC-707389
Eisai Material Numbers	190232
Manufacturer/Supplier	Eisai Inc. Woodcliff Lake, NJ 07677
Telephone Number	877-973-4724
24 Hour Emergency Number	CHEMTREC 800-424-9300 Internationally 703-527-3887
Fax Number	201-746-3207

Occupational Exposure Limit (OEL) for the active ingredient: 0.1 µg/m³ Acceptable Surface Limit (ASL) for the active ingredient: 0.05 µg/cm²	
Potential Health Effects:	
Routes of Entry	Ingestion, Inhalation, Skin contact/absorption, Injection, Eye Contact
Inhalation	No information regarding inhalation

Section 6 Accidental Release Measures

Prevent migration into the environment. Absorb material and place waste into appropriate container, being careful to prevent contact with broken glass (e.g., utilize a tool to pick up broken glass). Wipe the spill area several times (3 times minimum) with 100% Ethanol. Appropriately discard all clean up materials per local, state, and federal regulations.

For significant liquid spills or spills in a dried state, appropriately trained personnel must use Level B protective safety gear as well as a Powered Air Purifying Respirator (PAPR) or a Self Contained Breathing Apparatus (SCBA) with full facepiece operated in positive pressure mode. Clean up spills in a manner that does not aerosolize the spilled material. Utilize the same methods as described above for absorbing spills, utilizing 100% Ethanol, and discarding of waste.

