# Index

Index terms	Lin	<u>nks</u>
Α		
advanced packaging technologies	192	
aerosols	145	
ampoules	183	
animal quarters	399	
aseptic transfer	392	
autoclaving	138	
automated production systems	190	
В		
bio-pharmaceuticals		
cGMP	376	
change control	383	
cleaning processes	434	
containment	393	
equipment design	424	
laboratory design	421	
personnel considerations	394	
pilot plant design	375	417
	424	
primary production	388	398
process control	393	
product recovery and purification	394	
regulations	373	
retesting	415	
sampling	439	

## Index terms

448

bio-pharmaceuticals (Continued)	
secondary production	402
sterilization	430
validation	377
biosafety cabinets	426
blister packs	179
bottle packs	178
bulk pharmaceutical chemical production	75

<u>Links</u>

## С

capping	184	
capsules production	125	
cartoning	185	
case packing	186	
cell disruption	83	
centrifuging	83	91
change control	206	
bio-pharmaceuticals	383	
system	71	
chromatography	84	
Clean In Place (CIP)		
design	290	
validation	65	
clean steam	281	
cleaning	164	
coating processes	123	
coding	185	
compressed air	274	288
computerized systems		
design criteria	32	
validation	68	

		449
Index terms	Li	<u>nks</u>
consumables storage	265	
containment	176	
contractors	300	
COSHH	245	
creams	133	184
cross-contamination	160	
bio-pharmaceuticals	412	
setting limits crystallization	64	88
current Good Manufacturing Practice		
bio-pharmaceuticals	376	
design requirements	22	
Directives	13	
maintenance	262	
D		
delayed release	147	
direct compression	119	
dispensing	149	
distillation	87	
drug approval process	10	
drug master files	11	
dry heat sterilization	140	
drying	91	
Ε		
effluent treatment	291	
effluents		
gaseous	293	
liquid	294	
solid	297	
electrodialysis	83	

#### 450

Index terms	Li	<u>nks</u>
elixirs	132	
emulsions	132	
endotoxins	402	
environmental classification	167	
equipment cleaning	164	
equipment design criteria	30	
equipment flow criteria	29	
ethylene oxide sterilization	141	
extrusion	130	
F		
fault tree analysis	227	
fermentation	78	
media sterilization	82	
рН	81	
sterile design	81	
temperature control	82	
fermenters		
gas-lift	79	
open tank	78	
sparged-tank	79	
stirred tank	79	
filters	89	144
form-fill-seals	183	
formaldehyde	140	
fume cupboard design	313	330
G		
gelatin capsules		
hard	126	

 hard
 126

 soft
 129

	451
Index terms	Links
genetically engineered organisms	398
Good Clinical Practice	20
Good Laboratory Practice	20
granulation	95
Н	
handover	58
hard gelatin capsules	126
hazards	
chemical reaction	237
dust explosion	240
environmental	246
fire and explosion	238
laboratories	251
occupational health	241
pilot plants	252
HAZOP	215
heat transfer oils	286
high-intensity pulsed light	143
human reliability estimation	227
HVAC systems design	272
hydrogen peroxide	141
I	
injections	136
inoculation transfer	392
intermediate bulk containers	86
irradiation	143

## L

153 185

452		
Index terms	Li	nks
laboratory air handling	340	
laboratory balance and instrument benches	328	
laboratory bench design	321	
laboratory extraction hoods	336	
laboratory fume cupboards	329	
laboratory fume extraction	337	
laboratory general design	307	
laboratory safety	344	
laboratory service spines	326	
laboratory tables	329	
laboratory trolleys	329	
layout and building design, principles	154	
lighting selection	175	
lyophilization	407	
Μ		
maintenance, building design	263	
maintenance, cGMP	262	
material flow criteria	29	
materials management systems	153	
microencapsulation	148	
milling	95	
Ν		
New Drug Application (NDA)	11	
nitrogen	283	288
nucleic acids	401	

## 0

occupational health exposure limits (OELs)	241
hazards	241

		453
Index terms	Li	nks
occupational health exposure limits (OELs) (Continued)		
legislation	244	
ointments	133	184
ophthalmic preparations	135	
Orange Guide	38	
over-sealing	186	
Р		
packaging, BPC	95	
packaging operations	177	
palletizing	186	
pellets	129	
peracetic acid	140	
personnel flow criteria	29	
pharmacovigilance	13	
pills	111	
pilot plants		
chemical synthesis	361	
dispensaries	371	
final formulation and packaging	369	
optimization	371	
physical manipulation	368	
safety	371	
planned maintenance	301	
plant records	298	
post-marketing drug evaluation	13	
postscript technology	197	
powder filling systems	181	
preventative maintenance	301	
process development		
building design	356	

## Index terms

454

process development (Continued)	
design principles	347
process optimization	58
product segregation	163
product sterilization	138
production area workshops	297
production automation systems	96
pyrogens	402

## Q

qualification	
Design Qualification (DQ)	53
Installation Qualification (IQ)	55
Operational Qualification (OQ)	56
Performance Qualification (PQ)	59
protocols	51
quality control laboratories	305

## R

reaction, biotechnology	77
reaction, chemical synthesis	76
refrigeration	286
regulatory environment, UK	12
reliability centred maintenance	301
residual contaminating proteins	400
residual host cells	400
revalidation	72
bio-pharmaceuticals	383
risk assessment	
criteria	228
environment	250

	455
Index terms	<u>Links</u>
risk assessment (Continued)	
laboratories	251
pilot plant	252
preliminary hazard analysis	212
principles	211
S	
sachets	180
services and utilities	
design criteria	26
sizing	287
specification	270
SHE	
inherent	209
integrated management	204
legislation	257
sieving	95
site layout	
brownfield sites	107
greenfield sites	101
small scale pilot facilities	352
soft gelatin capsules	129
solids drying	91
solids filtration	89
solvent recovery	95
sonocrystallization	88
specialist water supplies	
de-ionised water	284
purified water	284
towns water	284
WFI	284
spheronization	130

456	
Index terms	<u>Links</u>
spray granulation	117
sprays	135
Steam in Place	290
sterile filtration	144
Sterilize in Place	290
storage, consumables	265
suppositories	134
surface finishes	173
suspensions	132
sustained release	147
syringes	183
syrups	132
Т	
tablets	112
coating	123
compression	119
granulation	112
tubes	182
U	
ultrafiltration	83
ultraviolet light	143

### V

vacuum	279
validation	
analytical methods	71
bio-pharmaceuticals	377
cleaning	61
computer systems	68

Index terms	457	
	<u>Links</u>	
validation (Continued)		
directives	38	
flow chart	49	
policies and procedures	41	
process	60	
retrospective	61	
of CIP systems	65	
Validation Master Plan (VMP)	44	
ventilation systems	171	
vials	183	
viruses	401	
W		
warehousing	188	

warenousing	100
waste regulatory requirements	292
waste treatment	291
Water for Injection (WFI), system design	28