

Index

a

- absorption (of an active substance) 146
- absorption spectrum 125
- accelerated stability study 113
- acceptance (econ.) 317
- acceptance criteria
 - analytical 104
 - contractual 385
- access control 199, 209
- accuracy 114
- acetic acid 119
- action of a drug 144
- active pharmaceutical ingredient 37
- activity assay 109
- actual account 330
- addiction 150
- additional services 315
- adenosine-triphosphate 20
- administration 255
- adsorbent 76
- adsorption-desorption mechanism 81
- adsorption process 29, 76
- adverse drug event 165
- adverse drug reaction 165
- aeration 56, 285
- aerobic respiration 20
- aerosol 96
- affinity chromatography 85, 107, 123
- affinity gel 92
- agarose-dextrane material 92
- aggregation 29, 109
- air changes 295
- air duct 295
- air filter 295
- airlock 19, 292
- air shower 292
- alanine 98
- alarm threshold 306
- algae 17
- allocation key 331
- allowance factor 309
- aluminum-oxide 94
- ambient air 291
- ambient temperature 283pp
- amino acid 25
 - analysis 108, 115
- amphoteric behavior 30
- amplification steps 48
- ampoule 97
- anabolism 20
- analogue data 152
- analysis of primary structure 107
- analytical artifact 182
- analytical chromatography 123
- analytical report 210
- analytical transfer 385
- analyzer 126
- animal experiment 154
- animal husbandry 46, 61
- animal model 130
- anion exchanger 85
- annuity 369
- antibiotics 16, 72
- antibody 28, 122
- anticounterfeiting 100
- anti-foaming agent 72, 137
- antigen 121
- antigen-antibody reaction 122
- API-plant 256
- API production 37
- apoptosis 22
- appearance 98
- application patent 325
- aqua purification 279
- aqueous phase 89
- archae bacteria 17

- area under the curve (AUC) 149
- Aspergillus niger* 44
- assessment matrix 361
- association 29
- asymmetrical membrane 94
- attenuation 12
- audit trail 186, 209
- automation of water systems 284
- availability of oxygen 49

- b**
- baby-hamster kidney (BHK) 45
- bacteria 17, 110, 129
- balance of interests 312
- base 31
- baseline separation 124
- basic engineering 303
- basis of design 205
- batch adsorption 76
- batch culture 50
- batch documentation 211
- batch mode 50
- batch number 209
- batch-record review 209, 212
- batch-to-batch cleaning 202
- bed height 93
- beta elimination 29
- Betaferon® 45
- beta-sheet structure 125
- bidding process 312
- bid-proposal preparation 338
- binding affinity 73
- binding offer 349
- bioavailability 146
- bioburden 53
- bioburden controlled 71
- bioburden reduction 66
- biogenerics 138
- biological activity 27, **109**
- biological barrier 146
- biological clock 47
- biological effect 109
- biological hazard 288
- biological license application 242
- biological membrane 146
- biological safety class 269
- biological variability 154
- biomass 49
- bioreactor 56
- biosuspension 71
- biotech working party 232
- blinded study 162
- blood-brain barrier 146
- blood cells 56
- blood circulation 146
- blood fractionation 13
- blood serum 62
- boiler 291
- book value 337
- bottleneck analysis 374
- bovine serum 62
- bovine spongiform encephalopathy (BSE) 137
- break-even point 325
- bridging study 376
- bridging trial 160
- budget request 309
- buffer exchange 69
- buffer-preparation area 88, 254
- buffer solution 39
- building automation-system (BAS) 297
- building drawings 304
- building laws 318
- building regulations 317
- building shell 294
- build-or-buy 361
- bulk filling 39
- Bundesinstitut für Arzneimittel und
Medizinprodukte (BfArM) 233
- butanol 89
- byproduct 49

- c**
- calculation surcharge 316
- calibration 114
- campaign mode 273
- cap 99
- capacity usage 372
- capillary electrophoresis 118
- capital commitment 261
- capital costs 335
- capital demand 353
- capital interest 366
- capital investment 273
- capital value 368
- carbohydrates 31
- carbohydrate structure 127
- carbon dioxide 62
- carbon source 61
- carcinogenicity 165
- cardiovascular system 156
- carry-over 198
- cartridge filter 79
- cascade concept 268
- case report form 160
- catabolism 20
- cation exchanger 92
- ceiling-air inlet 295
- ceiling diffusor 295

- cell
 - activity 49
 - debris 70
 - density 49, 41
 - dry weight 26
 - expansion 47
 - growth 49
 - growth-rate 372
 - lifetime 48
 - nucleus 19
 - retention system 51, 52
 - substrate 38pp, 47
 - viability 132
- cell bank 46
- cell culture 130
- cell-culture medium 62
- cell division 22
- cell line 45
- cell mass 50
- cell separation 73
- cell therapy 13
- cellulose 31
- center effects 161
- Center for Biologics Evaluation and Research (CBER) 230
- Center for Devices and Radiological Health (CDRH) 230
- Center for Drug Evaluation and Research (CDER) 230
- central compartment 146
- central nervous system (CNS) 156
- centrifugation 73
- certificate of analysis 183, 212
- certificate of compliance 183, 212
- chain-termination method 128
- chamber filter-press 74
- change control 185
- change management (engineering) 316
- change management (quality) 210
- change-over investment 357
- change request 215
- change requiring regulatory approval 214
- change of scope 316
- charge/mass ratio 117, 126
- chemical compatibility 277
- chemical inactivation 90
- chemical ionization (CI) 126
- chicken eggs 46
- China Food and Drug Administration (CFDA) 236–237
- Chinese hamster ovary (CHO) 45
- chlorination 281
- chromatogram 124, 133
- chromatography 81
 - gel 91
 - skid 88
- chromosome 21, 25
- cleaning in place (CIP) 275, 290, 283
- cleaning out of place (COP) 290
- CIP-return line 64
- circular dichroism 130
- claims management 315
- clarity 112
- classified environment 199
- clean room 289
- clean steam 285
- clean utilities 278
- cleaning agent 57
- cleaning area 266
- cleaning procedure 289
- cleaning protocol 289
- cleaning validation 207
- cleanliness class 290pp
- cleanliness requirements 257
- clean-room cascade 199
- clean-room class 197, 258
 - clothing 197
 - concept 263
 - finishing 291
 - monitoring 32
- clearance 148
- client-manufacturer relation 184pp
- climate chamber 207pp
- clinical endpoint 154
- clinical trials 105, 154
 - application 242
 - directive 194, 217
- closed process 199
- comedication 165
- Code of Federal Regulations (CFR) 230
- codon 24
- codon usage 25
- cold chain 207
- cold processing 42
- cold spot 282
- cold storage 260
- cold withdrawal 283
- colony-forming unit 129
- color 112
- color particle 136
- column-packing station 89
- combined production 348
- commercial supply 374pp
- commissioning 305
- Committee for Medicinal Products for Human Use (CHMP) 232

- Committee for Medicinal Products for Veterinary Use (CVMP) 232
 - Committee for Orphan Medicinal Products (COMP) 232
 - common technical document 238
 - comparability 215pp
 - comparability protocol 215
 - comparability study 160, 384
 - comparative trial 159
 - comparison of profitability 367
 - compartment (body) 146
 - compartment (environment) 318
 - compedial water quality 279
 - complaint 184
 - complex media 62
 - computer validation 208
 - concept engineering 303
 - conceptual design 260
 - concomitant administration 150
 - conductivity measurement 136
 - confidentiality 312, 315
 - confidentiality agreement 312
 - conflict resolution 380
 - conformance runs 206, 308
 - consideration 312
 - construction costs 310
 - construction time 308
 - consumable 266
 - contact inhibition 22, 56
 - contact switches 277
 - contamination 198pp
 - content 106
 - contingency 310
 - continuous cell line 22
 - continuous mode 50
 - contract design 312
 - contract manufacturer 377
 - contract negotiation 378
 - contract partner 188pp
 - contract review 188pp
 - contractor 311
 - contractual risk 313
 - contraindication 150
 - contribution margin 351
 - control group 167
 - controlled environment 199
 - cooling loop 286
 - cooling media 286
 - cooling tower 286
 - Coomassie blue 119
 - cooperation structure 378
 - core process 253
 - corn 46
 - corrective action 182, 186, 212
 - corrective action—preventive action (CAPA) 212
 - cost
 - accounting 329
 - allocation 330
 - comparison 367
 - control 379
 - estimate 304, 309
 - function 349
 - risk 325
 - cost center accounting 333
 - cost-distribution sheet 348
 - cost inertia 331
 - cost model 338
 - cost of piping 309
 - costs-by-cause principle 331
 - costs of labor 310
 - cost structure analysis 349
 - cost type accounting 333
 - cost unit accounting 334
 - counter ion 85
 - Creutzfeldt–Jacob disease 137
 - critical observations 186
 - critical parameter studies 42
 - critical path 308
 - critical system 306
 - cross contamination 198
 - crossover study 162
 - cryoconservation 47
 - cryoprotectant 98
 - crystallization 89
 - cumulation 149
 - currency risk 298
 - current GMP 191
 - cytoplasm membrane 19, 32
- d**
- 2D matrix code 100
 - 6-D rule 282
 - data accessibility 209
 - data-archiving system 208
 - data safety 209
 - dead volume 282
 - dead-end filtration 73
 - deamidation 29
 - Dear Doctor letter 169
 - death kinetics 54
 - decanter 73
 - dedicated plant 273
 - deep-freeze system 278
 - degradation product 49, 70, 113
 - degree of automation 270
 - dehumidification 295
 - deionization 62

- deionized water 280
- demand peak 392
- denaturation 108
- Department of Health and Human Services 229
- depreciation 335
- depth filtration 79
- desalting 62
- design control 177
- design qualification 204
- design validation 189
- design verification 189
- desorption 76
- desoxy-nucleotide-triphosphate 128
- destruction 184
- detail engineering 303
- development agreement 380
- development report 210
- deviation 210
- deviation investigation 210
- deviation management 211
- deviation report 210pp
- dextrane 94
- diabetes 14
- diafiltration 39, 72
- dictyosomes 20
- differential scanning calorimetry 131
- DIN 227
- DIN ISO 9000 176
- direct-capture chromatography 78
- direct costs 329
- direct-impact system 306
- discoloration 112
- displacement flow 292
- disposable bag technology 277
- dissolved oxygen 132
- distillation 281
- distribution 146
- disulfide bridge 26, 106, 118
- dithiothreitol 118
- DNA sequencing 128
- document control 211
- document transfer 385
- documentation 209
- documentation for regulatory permits 318
- donor anamnesis 137
- dose-finding study 159
- dose recommendation 154
- dose-response relationship 144
- dossier 242
- double blinding 162
- double peak 124
- doubling time 22, 45
- downstream 39
- drinking water 62
- drug
 - allergy 165
 - approval 242
 - interaction 150
 - product 37
 - safety 164, 184
 - study 154
- e**
 - Echerischia coli* (*E. coli*) 44
 - Edman degradation 116
 - effect of investment 357
 - effective dose (ED₅₀) 151
 - efficacy 144
 - electrical power supply 287
 - electronic batch record (EBR) 208, 297
 - electronic signature 209
 - electrospray ionization (ESI) 126
 - electrophoresis 118
 - elimination 147
 - eluate 82
 - elution buffer 82
 - elution step 82
 - EMA 231
 - emergency-power generator 288
 - endoplasmic reticulum 19
 - endotoxin 129
 - endotoxin load 70
 - energy balance 304
 - engineering run 307
 - enhanced design review 306
 - environmental legislation 318
 - environmental monitoring 135
 - environmental protection 318
 - enzymatic reaction 121
 - enzyme-linked immunosorbent assay (ELISA) 122
 - episomal plasmid DNA 44
 - Epogen® 46
 - equilibration 82
 - equipment cleaning 289, 373
 - equipment layout 304
 - Erythropoietin 14
 - escape door 258
 - ethical responsibility 324
 - ethics committee 160
 - Eudralex 233
 - eukaryotic cell 19
 - European Directorate for the Quality of Medicines (EDQM) 232
 - European Pharmacopoeia (PhEur) 233
 - European Union 231
 - evaluation software 124
 - excipient 195
 - exclusion criterion 161

- excretion capacity 147
- excretion organ 147
- executed batch record 209
- exhaust-air scrubber 289
- expandability 262
- expanded bed adsorption 77
- expansion areas 274
- expansion investment 357
- exponential growth 49
- expression strength 49
- expression system 43
- external service 335
- extinction 125
- extinction coefficient 108
- extracellular expression 44
- extracellular fluid 146
- extraction 89

- f**
- facade area 274
- Factor VIII 14, 52
- factory acceptance-test (FAT) 307
- failure costs 175
- failure mode and effect analysis (FMEA)-analysis 184
- failure prevention 181
 - costs 175
- failure root-cause 181
- fast-atom bombardment (FAB) 126
- fast-track review 242
- fast-track status 327
- fatty acids 32
- feasibility study 304
- fed batch mode 52
- Federal Register 226
- fee-for-service contract 313
- fermentation 48
 - analytics 132
 - area 260
 - capacity 372
 - conditions 35
 - course 57
 - debris 289
 - titer 41
 - volume 67
- fetal bovine serum 137
- fields of activity of ISO 9000 176
- Filgrastim 153
- filling 96
- filling level 57
- filter
 - cake 74
 - cassette 74
 - cloth 74
 - residue 74
 - test 63
- filtration 73
- filtration membrane 94
- final container 98
- final formulation 280
- final purification 80
- final rinse 207, 289
- final treatment step 280
- financial planning 353
- finished product 101
- fire code 317
- fixed costs 331
- fixed investment 356
- fixed unit costs 332
- flexibility 269
- flexible hose 275
- flexible piping 275
- flocculation 71
- floor plan 259
- flow rate 92
- flow resistance 92
- flow visualization, smoke study 295
- fluidization 78
- fluidized bed reactor 60
- foam control 58
- foaming 57
- folding 26, 107
- folding box 97
- follow-up investment 273, 357
- follow-up product 113
- follow-up stability study 113
- food and drug administration (FDA) 299
- form of administration 96
- formulation buffer 97
- formulation 96, 134
- fouling 79
- fractal plant 274
- fraction 82
- fraction collection tank 82
- fractionation 125
- Freedom of Information Act 230
- functional description 205

- g**
- gastrointestinal tract 153
- gel electrophoresis 118
- gel-filtration chromatography 85
- gel-permeation chromatography 72
- gel staining 118
- gene expression 19
- gene sequence 108
- gene therapy 13
- gene vector 24

- general contractor 312
 generic drug 138
 genetic code 24
 genetic instability 48
 genetic stability 22
 genetically modified organisms 288
 genome 44, 129
 genotype characterization 17
 Gerstmann–Straeussler syndrome 137
 glass ampoule 97
 glycine 98
 glycoanalytics 127
 glycogen 31
 glycolipid 31
 glycolysis 20
 glycoprotein 31, 127
 glycosylation 26, 14
 glycosylation pattern 127
 genetically modified organisms (GMO)-free 266,
 288
 GMP flows/diagram 263
 go/no-go criterion 358
 gold standard 327
 golgiapparatus 78, 200, 360
 good automated manufacturing practice 174
 good clinical practice 174
 good engineering practice 174
 good laboratory practice 174
 good manufacturing practice (GMP) review 189,
 191
 good storage practice 174
 good tissue practice 174
 gowning 197
 gowning area 293
 gradient elution 88
 gram staining 17, 130
 grant of a patent 325
 granulocyte colony-stimulating factor
 (G-CSF) 153
 granulocyte macrophage colony-stimulating factor
 (GM-CSF) 14
 gross investment 357
 growth factor 62
 growth limitation 49
- h**
- half-life 148
Hansenula polymorpha 44
 hard piping 275
 head of manufacturing 196
 head of quality control 196
 healthy volunteer, test person 158
 heat sterilization 54
 heat supply 285
 heating jacket 57
 heating-circuit (-media,-steam) 285pp
 heat-transfer system 285
 heat, ventilation and air-conditioning (HVAC)
 installation 294
 heavy metals 279
 helical structure 108
 Herbal Medicinal Products Committee
 (HMPC) 232
 high-efficiency particulate air (HEPA)-filter 295
 high-pressure homogenization 75
 high-pressure liquid chromatography (HPLC) 87,
 95, 127, 374
 holding point (in the process) 39
 homogenizer 75
 horizontal design 260
 hormone 62
 horse-shoe crab 129
 host cell 43
 host cell protein 69pp
 host cell protein ELISA 122
 hot storage 282
 human growth-hormone 14
 human immunodeficiency virus (HIV) 24
 human insulin 27
 human serum albumin 137
 humidity 294
 Humulin® 45
 hurricane 300
 hybridization 127
 hydrogen bonding 118
 hydrolysis 29, 115
 hydrophobic interaction chromatography 86
 hydrophobicity 86
 hydroxy propyl methyl cellulose (HPMC) 98
 hygiene policy 197
 hypersensitivity reaction 165
- i**
- identity test 107
 idiosyncratic side effect 150
 immune system 156
 immunoelectroblot 121
 Immunologicals Working Party 232
 improvement process 196
 impurity 68
 impurity profile 109
 immunogenicity 26, 138
 inclusion body 18, 44
 inclusion criterion 161
 indirect impact system 306
 infectivity 130
 informed consent 161
 infrared spectroscopy 125

initial application 150
 injection site 153, 156
 inoculation 48, 256, 268
 inorganic salts 69
 in-process control (IPC) 132, 211
 installation qualification 205
 instrument air 285
 insulin 27
 integrated plant 274
 integrator 124
 interest rate for calculation 364
 interface management 378
 International Conference on Harmonization (ICH) 237
 International Society of Pharmaceutical Engineering (ISPE) 238
 interferon 14
 interleukins (ILs) 14
 intermediate 195
 intermediate precision 114
 intermediate release 106
 internal rate of return 368
 intracellular expression 44
 intravenous injection 146
 inventory management 392
 investigational drug 216
 investigational medicinal product dossier 242
 Investigational New Drug (IND) application 242
 investigations operations manual 241
 investment
 – appraisal 365
 – calculation 365
 – costs 309
 – decision 357
 – planning 362
in-vivo stability 153
 ion concentration 70
 ion-exchange chromatography 85
 ion exchanger 85
 ion-exchanger gel 91pp
 ionization 126
 ion source 126
 IPC analytics 254
 IPC lab 132
 IP safety 300
 irrelevant costs 333
 Ishikawa diagram 184
 ISO 238
 isoelectric point 119
 isoelectrical focusing 119
 isolation 80
 isolator technology 292
 isometric drawing 304

j

Japan Pharmaceutical Manufacturers Organization 235

k

key performance indicators (KPIs) 397
 kidney 147
 KIKO 235
 Kjeldahl 118
 know-how safety 300
 Kogenate[®] 46

l

labeling 40pp
 labor legislation 235
 laboratory information management system (LIMS) 208
 lag phase 50
 laminar air flow 292
 Lantus[®] 153
 large-scale process 385
 launch 324pp, 374pp
 leachable 69
 leaching 93
 lead time 308
 Lepirudin 14
 lethal dose (LD₅₀) 151
 Letter of Intent 312
 Leukine[®] 45
 liability 313
 liberation 146
 liberation – absorption – distribution – metabolism – excretion (LADME) 146
 license payment (royalty) 328
 life cycle 324
 life cycle of investment 354
 ligand 85, 92
 limit of detection 114
 limit of quantification 114
 limulus amoebocyte lysate (LAL) -test 129
 LIMS 208
 linearity 114
 lipid 109
 lipo-polysaccharide 31, 44, 70, 109
 liquid nitrogen 286
 liquidation value 364
 liver 147
 living cell mass 49
 loading capacity 372
 loading step 83
 local tolerance 156
 long-term side effect 165
 lower price-limit 329
 lymphatic system 146

- lump-sum contract 316
- lyophilisate 135
- lyophilization 98pp
 - cake 98, 153
- m**
- machine hour-rate accounting 347
- mad cow disease 137
- main drying 98
- main equipment list 310
- main peak 124
- main service 314
- maintenance costs 335
- major change 213
- major observation 187
- major variation 213
- make-or-buy 387
- make-up 41
- mammalian cell 45
- mammalian cell-culture 55
- manufacturing and supply agreement 380
- manufacturing costs 41, 160
- manufacturing documentation 209
- manufacturing license 233pp, 240pp
- marginal costing 346
- marker 121
- market exclusivity 326
- market release 211
- market saturation 324
- market share 323
- marketing authorization 234, 380
- mass spectrometry 125
- master batch record (MBR) 201, 210
- master cell bank (MCB) 47
- material airlock 200
- material balance 254
- material costs 335
- material flow 258
- material of construction 69, 94, 291
- matrix-assisted laser-desorption ionization (MALDI) 126
- maturation phase 324
- maturity of application 270
- Maxam–Gilbert method 128
- maximum tolerable dose (MTD) 151
- mechanical completion 303
- media
 - component 61
 - hold tank 62pp
 - prep tank 64
 - preparation 256
 - supply 63
- medical investigator 160
- medication error 166
- medium (fermentation) 61
- membrane bioreactor 60
- membrane module 60, 185
- mercaptoethanol 118
- metabolic system 35
- metabolism 20, 147
- method validation 114
- microbial contamination 129, 267, 280
- microbial count 54
- microfiltration 79
- microorganisms 17, 278, 301
- microparticle 153
- microtiter plate 123
- milk 46
- mill 75
- minimal therapeutic concentration 149
- minimal toxic concentration 149
- Ministry of Health, Labor and Welfare (MHLW) (Kosei-roudou-sho) 235
- minor change 214
- minor observation 187
- minor variation 214
- mitochondria 20
- mobile CIP-skid 276
- mock run 122
- mode of action 138
- model process 273
- model virus 91
- moderate change 214
- modular construction 275
- molecular weight 108
- molecular weight cutoff (MWCO) 80, 94
- monocellular layer 55
- monocentric 161
- monoclonal antibody 13, 29, 45
- mortality rate 154
- moss cell 46
- mouse-myeloma 45
- movable tank 276
- multicentric trial 161
- multiple application 149
- multi-purpose plant 202pp
- municipal sewer system 288
- municipal water 281
- mutagenicity 156
- mutation 22, 48
- mycoplasma 110
- n**
- nasal administration 152
- nasal mucosa 152
- National Health Surveillance Agency (ANVISA) 237
- natural disaster 300

- net cash flow 368
 - net charge 120
 - net costs 329
 - net investment 357
 - net present value (NPV) 365, 368
 - net profit 351
 - Neulasta® 153
 - neutralizing antibodies 156
 - new drug application 242
 - nitrocellulose matrix 120
 - noise protection 318
 - nominal accounting 330
 - nominal capacity 332
 - non-binding orientation bid 349
 - Northern blot 120
 - Note for Guidance 227
 - NovoSeven® 46
 - Novolin®45
 - NPH-insulin 153
 - NS0 45
 - nuclear magnetic resonance 108
 - nucleic acids 30
 - nucleotide building-block 128
 - nutrient medium 61
- o**
- obligation to co-operate 313
 - occupational health 318
 - Office of the Commissioner 230
 - Office of Regulatory Affairs (ORA) 230
 - Official Journal of the European Communities 226
 - Official Medicines Control Laboratories (OMCL) 233
 - off-label use 327
 - oil-free compressor 285
 - olfactory nuisance 288–289
 - once-through cleaning 290
 - OOS result
 - open process 199
 - open study 162
 - operating assets 337
 - operating costs 270
 - operating time 372pp
 - operational qualification 205
 - operational readiness 331
 - oral mucosa 153
 - organelle 19
 - organic phase 89
 - organic solvent 42, 89
 - organics 277, 288
 - organization schedule 308
 - orphan drug 242
 - orphan drug status 326
 - outer appearance 112
 - overall yield 67
 - overflow 372
 - overhead calculation 329
 - overhead costs 328
 - oxygen supply 62–63
 - ozonization 281
- p**
- package units 297
 - packaging 99, 134
 - packing homogeneity 89
 - paper-based documentation 296
 - parallel study 162
 - Parenteral Drug Association (PDA) 240
 - Pareto-analysis 184
 - parking-lot effect 164
 - particle 134, 295
 - particle filtration 79, 281
 - past pollution 318
 - patent protection 325
 - patient compliance 164
 - patient-information leaflet 97, 151
 - Paul-Ehrlich Institute (PEI) 233
 - payback time (static/dynamic) 367pp
 - peak area 124
 - peak height 124
 - peak profit 324
 - peak sales 324
 - peak symmetry 124
 - poly(ethylene glycol) (PEG) 153
 - peptide mapping 116
 - peptide pattern 116
 - peptide 26
 - perforated ceiling 295
 - performance management 396–398
 - performance qualification 206
 - periplasmic space 44
 - permit procedure 318
 - permit situation 299
 - personnel airlock 292
 - personnel flow 263
 - personnel hygiene 267
 - personnel investment 356
 - pH-adjustment 57, 281
 - phages 110
 - Pharmaceutical Affairs Bureau 235
 - Pharmaceutical and Food Safety Bureau (PFSB) 235
 - Pharmaceutical Inspection Convention/Scheme (PIC/S) 238
 - pharmaceutical legislation 225
 - pharmaceutical manufacturing 38
 - Pharmaceutical and Medical Devices Agency (PMDA) 235

- pharmacodynamics 149
- pharmacokinetics 146
- pharmacokinetics (PK)-profile 144
- pharmacopoeia 227, 233, 237
- pharmacopoeial quality 62
- pharmacovigilance 167
- Pharmacovigilance Agreement 380
- Phase IV 167
- phase of clinical trial 157
- phenomenon of acquired tolerance 156
- pH-gradient 119
- phosphoric acid 289pp
- photosensitivity 125
- photosynthesis 60
- pH-swing 90
- phylogenetic tree 18
- Pichia pastoris* 44
- pilot plant 375pp
- piping and instrumentation diagram
 - (P and ID) 304
- pivotal study 159
- placebo-controlled study 161
- placenta 146
- plant maintenance 258
- plant usage 331
- plaque test 130
- plasma 13
- plasma concentration 148
- plasma desorption 126
- plasmid 18
- plasmid DNA 44
- plastic tube 277
- platform technology 262, 273, 377
- point-of-use heat exchanger 282
- points to consider 227
- polarity 73
- pollen dispersal 61
- poly(ethylene glycol) (PEG) 89, 153
- polymer membrane 94
- polymerase 128
- polymerase chain reaction (PCR) 127
- polysaccharides 31
- pooling 374
- pore size 79, 93
- posttranslational modification 26, 107
- potatoe 46
- precipitation 29, 89
- precision 114
- preclinical study 156
- pre-fermenter 63pp
- prefilled syringe 97
- pregnancy 156
- preparation area 266
- preparative chromatography 81
- present value 368
- pressure
 - drop 92
 - gradient 267pp
 - test 63
 - vessel 57
- pressurized-air system 278
- prevalidation study 385
- price regulation 226
- pricing 327
- primary cell 15
- primary container 96, 112
- primary structure 26, 116
- primer 127
- prion 137
- priority review 242
- procedural segregation 257
- process
 - air 285
 - analytics 132
 - change 213
 - consistency 296
 - control 208, 296
 - control system 296
 - description 210, 254, 306
 - documentation 296
 - flow-diagram 259
 - optimization 389
 - patent 325
 - piping 276
 - support 254
 - validation 206
- processing time 63, 91
- process-related impurity 104
- procurement 176
- product
 - change-over 273
 - comparability 137
 - concentration 67
 - flow 263
 - instability 112
 - life-cycle 326
 - loss 66
 - patent 325
 - release 211
 - safety 257
 - stability 42
 - testing 105
 - yield 66
- production facility 253
- production fermenter 56
- product-related impurity 69pp
- product-related substances 69pp
- profit 324

profit and loss account 330
 profit comparison analysis 365
 profit margin 378
 programmable logic control 296
 project organization 311
 project time-plan 308
 prokaryotic cell 18
 Proleukin[®] 45
 promoter 19
 promotion 324
 proof of concept 376
 proof of principle (concept) 159
 prospective validation 208
 protease inactivation 76
 protease inhibitor 76
 protease 110
 protein-A chromatography 86
 protein aggregate 70, 75
 protein expression 43
 proteins 26
 protein-sequence analysis 116
 protein structure 27, 107
 proteolytic degradation 50
 Protropin[®] 45
 psychogenic effects 161
 pulmonary administration 152
 purchasing documents 302
 purification 39
 purification area 260
 purified water 62
 purity 109
 pyrogen 129

q

Quadrupol MS 126
 qualification 189, 203pp, 284pp, 305pp
 qualification protocol 204
 qualification report 204
 qualified person 197
 qualitative method 114
 quality assurance (QA) 211pp
 quality assurance agreement 187, **380**
 quality
 – control 212pp
 – deficiency 183
 – of life 154
 – management system 178
 – policy 185
 – system 176
 quality control (QC) 211pp
 quality control lab (QC-lab) 297
 quality working party 232
 quantitative method 114
 quaternary structure 27

r

rapid-alert system 169
 rapporteur 232
 rationalization investment 357
 raw material 61, 195
 raw-material testing 136
 recall 169, 184
 receptor 17
 recombinant protein 10
 Recombinate[®] 46
 recommittal rate 154
 re-examination 175
 reduction factor 91
 reference project 377
 reference sample 125
 reference standard 110
 reference substance 207
 Refludan[®] 45
 refolding 74
 regulatory affairs 210pp
 regulatory approval 376
 regulatory dossier 188
 regulatory inspection 238
 regulatory procedures manual 241
 release behavior 153
 release certificate 209
 release specification 104
 release status 255
 relevant costs 333
 reliability 254
 repeatability 114
 replacement problem 360
 reprocessing 183
 reproducibility 114
 reservation fee 387
 residence time 145
 residual moisture 110
 residual solvent 110
 resolution 91
 respiratory tract 152
 restriction enzyme 128
 retention capacity 94
 retention time 124
 retrospective validation 208
 retrovirus 71
 reverse osmosis 280
 reverse transcriptase 128
 reversed phase chromatography
 85pp
 review phase 359
 rhizosecretion 60
 ribosome 19
 right of continuance 273
 right to use 358

- risk
 - analysis 138
 - assessment 288
 - communication 184
 - control 185
 - of flooding 300
 - identification 184
- risk-based approach 184
- risk-benefit assessment 143
- risk-management process 184
- robustness of the manufacturing process 42
- rodent 156
- roller bottle 59
- room air 291pp
- room book 304
- room-in-room concept 294
- root-cause analysis 212
- route of administration 96
- routine audit 186
- routine operation 295

- s**
- Saccharomyces cerevisiae* 44
- saccharose 98
- safety interlock 206
- safety stock 43
- safety working party 232
- salt content 82
- sample port 132
- sample-size calculation 161
- sampling 284pp
- sandwich ELISA 123
- Sanger–Coulson method 128
- sanitization 56
- saturation phase 325
- scalability 277
- scale-up 384
- scale-up step 39
- scale-up study 384
- scaling method 362
- scientific advice 243
- scope of work 313pp
- search phase 358
- second supplier 393
- secondary drying 98
- secondary packaging 98
- secondary structure 27
- sector field 126
- seed train 47
- segregation steps 257
- selection problem 360
- self sanitizing 282
- self-draining system 282
- semi-finished goods 101
- sensitivity analysis 365
- separation principles 64
- separation zone 83
- sequence ladder 128
- serum 62pp, 137
- shake flask 39
- shear stress 55
- side effect 150
- sight glass 132
- silica gel 92
- silver-nitrate solution 119
- singular event 184
- site acceptance-test (SAT) 307
- site location factor 298
- size-exclusion chromatography 87
- small-scale model 385
- smoke study 295
- sodium dodecylsulfate 116
- sodium dodecylsulfate–polyacrylamide gel electrophoresis (SDS–PAGE) 118
- sodium hydroxide 57, 291
- solid-liquid extraction 89
- solid waste 288
- solubility of proteins 29pp
- solubilization 74
- solubilizing agent 75
- solvency 354
- source of contamination 282
- southern blot 120
- special permit 299
- specifications
 - analytical 104
 - devices 42
- specificity 114
- spectrophotometer 125
- spectroscopy 125
- spectrum 125
- spectrum of byproducts 35pp
- spine, backbone 274
- sponsor 160
- spray ball 57
- sprinkler system 258
- stability 112
- stability of the expression system 48
- stability data 376
- stability profile 112
- stability test 255
- stabilization 75
- stainless steel technology 54
- standard costing 346
- standard operating procedure 179
- standard technology 377
- standard therapy 162

starting culture 192
 starting material 195
 state of the art 226
 statistical methods 178, 185
 statistical relevance 161
 steam
 – condensate 285
 – distribution 285
 – sterilizability 282
 – sterilization 54
 – trap 291
 steering committee
 stem cells 16
 step yield 67
 sterile filter 64
 sterile filtration 90, 199
 sterile gases 285
 sterile manufacturing 268
 sterile technology 53
 sterility 53
 sterilization in place (SIP) 57, 290
 sterilization method 53
 sterilization time 54
 stirred bioreactor 55
 stirrer rotational speed 132
 stopper 98pp
 storage buffer 97
 storage conditions 113
 strategic investment 353
 street clothing 266
 structural data 107
 study design 155
 study protocol 160
 subcontractor 311
 subcutaneous injection 153
 subloops 282
 success of cleaning 289
 sugar chain 108
 sugar molecule 127
 supernatant 39
 supplementary protection certificate 325
 supplier qualification 187
 supply chain 391
 supply-chain management 392
 supply safety 393
 surface filtration 78
 suspension culture 56
 symmetrical membrane 94
 symmetry test 89
 synthetic medium 62
 syringe 97
 system wall 294
 systemic application 147

t
 tactical investment 357
 tangential flow filtration 78
 target location 144
 target profile 154, 327
 tax incentives 298
 technical complexity 270
 technical risks 313
 technical specification 302
 technology transfer 384
 temperature logger 207
 tender vetting 330
 teratogeny 156
 term sheet 312
 terminal sterile filtration 268
 termination of a contract 315
 termination fee 387
 tertiary structure 35
 testing costs 175
 testing status 177
 therapeutic dose 151
 therapeutic window 149
 thermal bridge 55
 thermal inactivation 76, 90
 throughput 91
 time-concentration curve 148
 time of flight (TOF) 127
 time point of investment 375pp
 time-point of market approval 112
 time-to-market 113
 tissue culture 57
 tissue engineering 15
 tissue-plasminogen activator 14
 titer 41
 tobacco plant 46
 tolerable impurity 138
 tolerance formation 156
 tooth-brush effect 164
 topical application 147
 total body water 146
 total organic carbon (TOC) method 136
 total protein content 107
 total spectrum of activity 150
 toxicity of metabolites 49
 toxicity 156
 toxicology 156
 traceability 99
 training 185, 197
 transcription 25
 transfection 24
 transfer panel 275
 transformed cell line 15
 transgenic systems 46
 translation 25

- trans-membrane flow 79pp
 - trans-membrane pressure 133
 - transmissible spongiform encephalopathie (TSE) 137
 - transmission electron microscopy (TEM) 130
 - transport conditions 113
 - transport protein 26
 - transport validation 207
 - trehalose 98
 - trend analysis 185
 - triplet 24pp
 - turbulent flow 295
 - two phase extraction **89**
 - type A, B, C, D-reactions 165
- u**
- ultra/diafiltration 79
 - unidirectional personnel flow 266
 - unit costs 333
 - unit profit 350
 - United States Pharmacopoeia 237
 - upfront investment 262
 - upstream 39
 - use point 283
 - useful economic life 364
 - user requirements 301
 - user requirements specification 204
 - utilities 278pp
 - UV-detection 84
 - UV/Vis spectroscopy 125
- v**
- vaccination 11
 - vaccines 11
 - validation 206
 - batch 377
 - master plan 208
 - protocol 208
 - report 208
 - run 307
 - value engineering 310
 - value-benefit analysis 361
 - variable costs 331
- vendor-managed inventory 394
 - verum 161
 - vial 97pp
 - virus 22
 - contamination 23
 - inactivation 90
 - load 90
 - production 11
 - reduction 90
 - testing 130
 - validation 91
 - visual inspection 134
 - V-model 204
- w**
- wage level 299
 - warehouse-management system 208
 - warning letter 230
 - warranty 315
 - washing step 82
 - waste flow 266
 - waste incineration 266
 - waste management 288
 - waste treatment 288
 - water 278pp
 - water for injection (WFI) 62
 - water solubility 73
 - western blot 118
 - wholesaler 163
 - wipe test 136
 - working cell bank (WCB) 48
 - World Health Organization (WHO) 238
- y**
- yeast extract 61
 - yeast 44
 - yield **41**, 66, 373
 - yield loss 68
- z**
- Zentralstelle für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG) 233
 - zoning concept 266

