

Exercise Two: Knowledge Domain Breakouts

"For the knowledge domain of compliance and quality, there are several areas of specific understanding, baseline knowledge or specific subject matter expertise that together would enable a person to effectively bring this knowledge to bear on the challenges and responsibilities that might arise on the job. What are the subject matter areas that underpin the 'Compliance and Quality' knowledge domain from your individual perspective?"

Focus Group 1	Focus Group 2	Focus Group 3	Focus Group 4	Focus Group 5	Focus Group 6
Good Manufacturing Processes (7)	GMPs (7)	GMPs and International (8)		Global GMP / regulatory understanding (EMEA, etc. beyond PDA) (9)	Record keeping, written documentation (5)
Current and Risk-based Validation (7)	Risk Management (4)	Quality Systems (8)		Corrective Action/ Preventative Action (4)	Ethics (6)
Ethics (5)	International Regulations (3)	Fundamentals of Validation (6)		Manufacturing process & system understanding (3)	Fundamental concepts of GMP & rationale for regs
Financial Compliance (3)	Validation and Qualification (2)	Quality by Design (3)		Change management (3)	Knowledge of government / industry guidance documentation (FDA process validation) (2)
Practical Applications within Industry (2)	Quality/Compliance (2)	Working in a Regulated Industry (2)		Investigation of failures (3)	Realities of working in regulated industry (1)
				Audit skills (like a regulator) (3)	Systems and tools for quality systems mgmt (1)
				Technical writing (3)	interpretation and implementation of regulatory guidelines (1)
				<i>Gap analysis techniques</i>	<i>Practical statistics</i>
				<i>Negotiation skills</i>	<i>Conceptual understanding global regs</i>
				<i>Observation skills</i>	
				<i>Interrogation skills</i>	
				<i>Good science (= good compliance)</i>	
				<i>Collaboration skills</i>	
				<i>Continuous improvement</i>	

Table A. Compliance Knowledge Domain

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Focus Group 1	Focus Group 2	Focus Group 3	Focus Group 4	Focus Group 5	Focus Group 6
Process Robustness (6)	Drug Development (7)	Molecule to Market (10)		Regulatory & product life cycle management (6)	Product Life Cycle (preclinical, clinical, commercial) (7)
Manufacturability (6)	Formulation (5)	Quality by Design (8)		PAT / process understanding / Quality by Design / Controls (5)	Technology transfer (manufacturability; points of hand-off) (6)
Particle Technology (4)	Process Analytical Technology (5)	Technology Transfer (8)		Scale-up /manufacturing feasibility (4)	Scale up (5)
Product Design (4)	Scale-up (3)	Biopharmaceutics (6)		Design of Experiments (4)	Identification of constraints, requirements & developing appropriate process, specifications in response (1)
Technology Transfer (2)	Technology Transfer (3)	Statistical Process Control (2)		Technology transfer (procurement, mat'l selection) (3)	Unit operations / design (1)
					Commercial optimization (relation to GMPs and regulations) (1)
				<i>Broad science knowledge as relating to process</i>	<i>Emergency technology (bioreactors, mixing)</i>
				<i>Project management</i>	
				<i>Statistics (validation)</i>	
				<i>Collaboration skills</i>	
				<i>Risk management</i>	
				<i>Equipment experience</i>	

Table B. Development Knowledge Domain

Exercise Two: Knowledge Domain Breakouts

Focus Group 1	Focus Group 2	Focus Group 3	Focus Group 4	Focus Group 5	Focus Group 6
Process Analytical Technology (7)	Manufacturing Technologies (8)	Process Troubleshooting (7)	FDA / other regulatory requirements (3)	Process knowledge, flow (6)	Process optimization (\$ versus throughput, regulatory requirements (6)
Emerging Technologies (6)	Forms (6)	Materials Management (6)	Health, safety, environmental awareness and risk assessment (3)	GMP / GXP / change control (5)	Unit operations - breakdown (bio focused) (5)
Process Optimization/Packaging (5)	Leadership People Skills (5)	Facility Design and Utilities (6)	Process understanding (at micro and macro scales - how, why, phases, steps) (3)	Manufacturing process controls, six sigma, process improvement (SPC) (5)	Emerging technologies, trends overview (PAT, sensors, green design) (3)
Lean Manufacturing (2)	Technology Transfer (2)	Six Sigma Lean Manufacturing (5)	Enterprise resource management systems (2)	Basic writing skills for industry (SOPs, records) (2)	Lean manufacturing (industrial engineering) (3)
People Skills (2)	Labor Relations (2)	Unit Operations (4)	Engineering for non-engineers (2)	Understanding consequences of deviations, variability (on quality, cost, safety) (2)	Critical Utilities (process and regulatory relationship) (2)
				Troubleshooting / investigation (2)	
				Compliance knowledge (2)	
				Industrial engineering skills (2)	
			<i>Supply chain management (relationship management, outsourcing)</i>	<i>Scale up</i>	<i>Process Analytical Technology (micro-detail)</i>
			<i>Understanding of Life Sciences</i>	<i>Reading equipment drawings</i>	
			<i>Shop floor management principles (think on feet, choose option, act)</i>	<i>General organizational understanding</i>	
			<i>Record keeping (batch records, documentation)</i>	<i>Technology transfer</i>	
			<i>Clean room protocols</i>	<i>Multidisciplinary teaming</i>	
			<i>Design & implementation of operator / technician training</i>	<i>Communication/ negotiation</i>	
			<i>Production planning (cycle time, cost of goods)</i>	<i>Compendal knowledge (USP, EP)</i>	
				<i>Data acquisition & analysis</i>	
				<i>Cost of goods understanding (conceptual)</i>	
				<i>Aseptic techniques</i>	

Table C. Manufacturing Knowledge Domain

Exercise Two: Knowledge Domain Breakouts

Focus Group 1	Focus Group 2	Focus Group 3	Focus Group 4	Focus Group 5	Focus Group 6
Outsourcing Third Party Relationships (8)	Strategic Planning (8)	Global Business Practices (7)		Sourcing strategies (procurement options) (5)	Vendor Relationship/ Mgmt (4)
Product Understanding (6)	Lean and Six Sigma Practices (5)	Network Strategies (7)		Sales and operations planning (supply & demand) (5)	Compliance aspects of all materials outsourcing (4)
Enterprise Resource Planning Systems (4)	Global Marketing (5)	Lean Sigma (5)		Inventory management (4)	Risk Management (3)
Lean Sigma (4)	Operational Research (4)	Logistics (5)		Supply and planning models (3)	Vendor qualification techniques/ processes (3)
Global Supply Chain Dynamics (4)	Supplier Quality Measurement (3)	Outsourcing (4)		Contracts and agreements (3)	Concepts of lean manufacturing, six sigma, value engineering (2)
				Contingency planning (3)	Inventory techniques (supply and demand, just in time, LIFO/FIFO) (2)
				Vendor selection/ relationship management (2)	
				<i>Broad understanding of science, product language, terminology</i>	<i>Product life cycle</i>
				<i>Material and resources planning (MRP)</i>	<i>Economics / contracts</i>
				<i>Distribution (master scheduling, cold chain)</i>	<i>Negotiation / contracts</i>
				<i>Finance</i>	<i>Understanding technical attributes and performance requirements</i>
				<i>Ethics</i>	<i>Business continuity planning</i>
				<i>Safety</i>	<i>Optimization</i>
				<i>RFP and RFQ processes</i>	<i>Documentation (global communication)</i>
					<i>Cultural business realities</i>
					<i>ERP systems</i>

Table D. Supply Chain Knowledge Domain

Exercise Two: Knowledge Domain Breakouts

Focus Group 1	Focus Group 2	Focus Group 3	Focus Group 4	Focus Group 5	Focus Group 6
Automation (8)	Aseptic Processing (8)	Pharmacology/Pharmacokinetics (7)		Development process understanding (6)	Microbiology/ cell biology (contamination, pathogenic, non-pathogenic) (4)
Control Parameters (7)	Containment and Isolation (5)	Design of Experiments (7)		Analytical tools (5)	Basics of cellular structure (manipulation techniques) (3)
Small vs. Large Molecule (7)	Purification and Separation (4)	Particle Sciences (5)		Problem solving techniques/ methods (5)	Cell line development (3)
Sterilization and Cleaning (5)	Safety and Environmental (3)	Analytical Techniques (4)		Experimental design (4)	Environmental, health and safety aspects of products (2)
Process Design and Science (1)	Process Design and Control (3)	Microbiology/bio-burden (3)		Understanding commercialization/ environment (4)	Stability (2)
				Intellectual property/ discovery (3)	
				<i>Observation / result</i>	<i>Basic biochemistry</i>
				<i>Collaboration skills</i>	<i>Processes for large molecule manufacturing</i>
				<i>Communication skills</i>	<i>Materials science</i>
				<i>GMPs / SOPs</i>	<i>Cell culture (equipment)</i>
				<i>Documentation skills</i>	<i>Physics of materials</i>
				<i>Prioritization/ decision-making</i>	<i>Sterility / aseptic</i>
					<i>Computational biology</i>
					<i>Application - guidance driving cell choices</i>
					<i>Understanding large molecule implications</i>
					<i>Pharmacokinetics / formulations</i>

Table E. Science Knowledge Domain

Exercise Two: Knowledge Domain Breakouts

Focus Group 1	Focus Group 2	Focus Group 3	Focus Group 4	Focus Group 5	Focus Group 6
Process Understanding (10)	Facility Design (6)	Unit Operations/Equipment (5)	Project mgmt (people skills, MS project) (3)	Concepts of facility design (Baseline Guides) (8)	Processes, unit operations and design (h&m transfer) (4)
Equipment Effectiveness/Six Sigma (8)	Project Management (5)	Project Management/CPMP (5)	Clean room, sanitary design (system principles, concepts) (3)	Equipment design (2)	Project management (3)
Process Reliability (5)	Good Engineering Practices (3)	Technology Transfer (5)	Automation, IT, controls, sensors (3)	Risk Management (2)	FMEA/ Risk Assessment (3)
Project Management (4)	Process Reliability (2)	Quality by Design/Facilities (4)	Six sigma, lean manufacturing (2)	Understanding end user requirements (2)	Facility design (critical utilities, flow of people, materials, waste) (3)
Automation (1)	Clean Rooms/Containment (1)	Process Control (4)	GMPs and requirements (2)	Communication (2)	V model for design; scope, user requirements, specifications etc. all linked to IQ,OQ,PQ, operations, SOPs (3)
				Engineering project management (2)	
				Change Management (2)	
				Commissioning / Qualification / Change Control (2)	
			<i>Health, safety, environmental (HSE), hazardous operations, containment</i>	<i>Design concepts and control</i>	<i>Engineering drawings/ documentation</i>
			<i>Product life cycle</i>	<i>Statistical knowledge</i>	<i>Change management</i>
			<i>Equipment understanding / maintainability concepts</i>	<i>Budgeting and schedules</i>	<i>Basics of finance, present value, project assessments</i>
			<i>Reliability centered maintenance</i>	<i>Troubleshooting</i>	<i>Clean room/ aseptic design</i>
			<i>Construction management</i>	<i>Understanding "operability" and maintenance</i>	<i>Equipment design (outputs for QA data)</i>
			<i>Validation / Commissioning / Qualification</i>	<i>Developing specifications</i>	
			<i>Process Scale-up / equipment eng.</i>	<i>Compliance knowledge</i>	
			<i>Technical writing of SOPs, manuals, procedures</i>	<i>General understanding of all engineering disciplines</i>	
			<i>Value Engineering</i>	<i>Contract negotiation</i>	
				<i>Vendor management skills</i>	
				<i>CADD</i>	
				<i>Excel competence</i>	
				<i>safety concepts</i>	
				<i>Basic engineering fundamentals</i>	
				<i>Process design fundamentals</i>	

Table F. Engineering Knowledge Domain

Exercise Two: Knowledge Domain Breakouts

Focus Group 1	Focus Group 2	Focus Group 3	Focus Group 4	Focus Group 5	Focus Group 6
Financial Knowledge (9)	Financial Management (5)	Financial Knowledge (10)	Leadership (taking ownership; creating clear goals; managing diversity in staff, culture, skills) (5)	Understands/ can use financial statements and budgets (6)	Leadership (cultures; org & people) (5)
Change Management (6)	Engineering Economics (5)	Business Ethics and Governance (6)	Communication - written, PPT (3)	Fundamentals of project management (5)	Organizational & professional development (3)
Risk Analysis (6)	Communication/Leadership (5)	Project Management Skills (6)	How to work in teams (manage conflict, find consensus, deal with complexity, take responsibility) (2)	Analytical skills (Excel proficiency) (4)	Financials (present value, applied proj analysis) (3)
Decision Making/Prioritization (3)	International Relations/Culture (4)	Industry Overview (2)	Strategic thinking (alignment, long term vs. short term, impact assessment)	Business culture/ behavior/ dealing with conflict (4)	Understanding Life Cycle of company (start up to global) (3)
Leadership and Relationships (2)	Risk Management (3)	Negotiation and Influence (2)	Product Life Cycle (including where elements are sourced) (1)	Organization theory/ how they work; formal vs. informal (2)	Life cycle of product (2)
			Finance (cost accounting, balance sheets) (1)	Leadership (having confidence) (2)	
				People management skills (2)	
				Intellectual property/ contract law (2)	
			<i>Negotiation</i>	<i>Enterprise Resource Systems</i>	<i>Working in teams (diversity)</i>
			<i>Project management</i>	<i>Negotiation/ Influencing</i>	<i>Personal mindset - take responsibility, be entrepreneurial, seek growth)</i>
			<i>Intellectual property, patent issues</i>	<i>Risk Management/ alliances</i>	<i>Manage change</i>
			<i>Sarbanes Oxley / Ethics</i>	<i>Business case modeling</i>	<i>Ethics</i>
			<i>KPIs in business</i>	<i>Setting/ aligning goals</i>	<i>Intellectual property (confidentiality)</i>
			<i>Global business concepts (finance, people, strategies)</i>	<i>Ethics</i>	<i>Decision making</i>
			<i>Understanding business goals (alignment with personal career goals)</i>	<i>Lean manufacturing, six sigma</i>	<i>Outsourcing /globalization</i>
			<i>Business development techniques / partnering</i>	<i>Decision making in ambiguous environments</i>	<i>Negotiation</i>
			<i>Outsourcing (make vs. buy, people, services)</i>	<i>Time management</i>	<i>Contracts</i>
			<i>How to write a business plan</i>	<i>"The art of listening"</i>	<i>Marketing</i>
					<i>Legal (deemed expert)</i>

Table G. Business Management Knowledge Domain