S!C johan@s-i-c.nl www.s-i-c.nl	GMP	&	LEAN – 6S
Doel	Kwaliteit: product effectiviteit en patiënt veiligheid.		Waarde creatie, reductie verspillingen en defecten.
Focus	Product. Minimale kans op β error, α error 'hoort erbij , kan gebeuren'. Binnen specificatie, compliant. Kwaliteit in het ontwerp van product en proces. Variabiliteit in proces 'hoort erbij '.		Proces. Streven naar perfectie in product en proces. Minimaal α error. Verminderen variabiliteit. In balans met productiviteit.
Materialen	Zekere supply chain, 'niet veranderen'. Voorraad in huis 'beschikbaar' na QP vrijgave. AQL.		Verbeteren op Quality, Leadtime, Technologie, Costs. Voorraad bij toeleverancier, pull, gekwalificeerde leveringen.
Mensen	Bewustzijn van voorschrift en procedures. Kwalificatie en training. QA is een afdeling, 'king', 'police'; over het gehele proces. Scheiden: denken en doen.		Medewerker suggesties welkom, deelname in verbeter proces. QA is voor ieder, in het proces.
Cultuur	'overmaat' mag, gelegitimeerde manier om variabiliteit op te vangen. Schouw uitval is acceptabel. Hoe kan de QP concluderen dat alles goed is ? QP vrijgave		Precies genoeg, variabiliteit aanpakken. Hoe kun je zien dat het proces goed is ? Geen defecten.
Verbeteren	Gereguleerd. Voorzichtig, continu. Productveiligheid.		Continu verbeteren. Stapsgewijze, KATA. Proberen & spelen.
Typische doelen	Gevalideerde processen, compliant. Afwijkingen corrigeren en voorkomen. Houdbaarheid en transport, GDP.		Productiviteit en kostenreductie. Cyclustijd en doorlooptijd. Voorraad niveau.
Project aanpak	GxP Validatie V Model: V-plan deel 1 volgorde, URS,FS, TS, Bouwen; V-plan deel 2 volgorde, testen, IQ, OQ, PQ, validatie rapport; Proces en procedure validatie; Apparatuur en mens kwalificatie.		DMAIC: Define, Measure, Analyse, Improve, Control. DMADV: Define, Measure, Analyse, Design, Verify. Validatation is part of 'design' phase. IDOV,Identify, Desing Optimize, Verify.
Hulpmiddelen	SOP en documentatie systeem voor borging. Veranderingen langs gebaande wegen: Change Control, project procedure. Validatie. Risico analyse. Audits en zelf inspectie. Trends, SPC. 100 % visuele inspectie 'schouwen'. Batch productie, grote batches is minder QP werk, line clearance. Reviews. Detectie van fouten.		5S: Scheiden Schikken Schoonmaken Standaardiseren Stimuleren. Standaardisatie ook voor leidinggevenden. Project management, Lean 6S aanpak. Veranderingen voorbereiden en direct uitvoeren. Risico's en mitigatie. Gemba walk. Processmap, VSM, DOE. Van 'push' naar 'pull', Flow, single piece flow, SMED. Visualisatie, verantwoording, klankborden tijdens dagelijkse meeting. Kaizen en AWO. Poka Yoke borging, ' engineer it out '. Voorkomen van fouten.

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Goal	Quality: product effectiveness and patiënt safety.		Value creation, waste & defect reduction.
Focus	Product. Minimal Chance on β error, α error 'can happen'. Meet specification, compliant. Quality build in, designed in product and process. Variability in processes is acceptable, ' is part of it '.		Process. Strive towards perfection in product and process Minimal change for α error. Reduce variability. Quality in balance with productivity.
Materials	Secured supply chain, 'do not change a winning combination'. Material on stock is only available after QP release. AQL.		Improve on Quality Lead time, Technology and Costs. Stock @ supplier, pull delivery, qualified supplies.
People	Know your instructions and processes, training and qualifiation. QA is an independent department, 'king', 'police'. Scope: the whole process. Separate 'think and do'.		Employee suggestions are welcomed, active participation in improvement processes, engagement, Q for all, according to Juran pyramid: QC and QI.
Culture	'Overplus' is accepted to compensate variability in the processes. Visual inspection 100 % or AQL technique is acceptable inclusive rejects. How can QP conclude that all is ok ?		Just enough, just in time, reduce variability. How can we all see that the process is working ? Zero defects.
Improve	Regulated. Carefull, continue. Productsafety, QA and RA constraints.		Continuous improvement. Step by step, KATA. Try and play. ' Try Storm' .
Typical goals	Validated processes, compliant. Corrective actions and preventive actions. Shelf life and transport GDP.		Productivity and cost reduction. Cycletime and thruput time. Inventory level control.
Project approach	GxP Validation V Model: V-plan down sequence: URS,FS, TS, Build; V-plan up sequence: testing, IQ, OQ, PQ, validation rapport; Process and procedure validation; Machine and people qualification.		DMAIC: Define, Measure, Analyse, Improve, Control. DMADV: Define, Measure, Analyse, Design, Verify. Validatation is part of 'design' phase. IDOV,Identify, Desing Optimize, Verify.
Techniques	SOP and documentation for sustainability and assurance. Changes according to Change Control procedure, project procedure. Validation. Risk analysis. Audits and self inspections. Trends, SPC, 100 % visual inspections or AQL. Batch production, optimal batch size ?, line clearance, engineered solutions. Reviews. Detection of mistakes.		5S: Separate, set in order, shine, standardize, stimulate. Standardisation for all, inclusive leaders. Project management, Lean 6S. Prepare change carefully, implement fast. Risk and mitigation. Gemba walk. Processmap, VSM, DOE. From 'push' to 'pull', Flow, single piece flow, SMED. Visualisation, accountability, standard leader work, daily stand up meeting. Kaizen en AWO. Prevention of mistakes, Poka Yoke,' engineer it out '.