

Manufacturing More Tomorrows<sup>™</sup>

# Holistic Design Principles That Collectively Meet the Need of the Current Market and Regulators Tomorrow and Over the Horizon Chad Hafer, Sr. Manager, Aseptic Operations

### Risk

- to the Micro

### Technology

- drive continual improvement of the manufacturing and control methods. (Annex 1)
- CCS has driven the building design from the Macro to the Micro



- processes can also be considered to eliminate direct human critical interventions. (Annex 1)

VCC – Verbal Cue Command MBR & EBR	RP-bas Pass co	ed Work Instruction – process task (8/10) overed filling needle over filling train	RP-based Oversight Guideline				
	Frame	Task description	Execution		Observation	Mitigation	
Remove filling needle sleeve – No touch of connect. of tubing with needle	8.1	<ul> <li>Remove the sleeve of the filling needle</li> <li>Carefully open the needle sleeve, being mindful NOT to touch the connection of tubing with needle</li> <li>Dispose the packaging material (sleeve) in waste box</li> </ul>	No Errors	•	Connection of tubing with needle touched while removing needle sleeve	Reject filling needle	
Inspect filling needle cover	8.2	Inspect covered filling needle, including tubing connection <ul> <li>Inspect the needle cover for potential damage</li> </ul>		_	Inspection of needle cover omitted	Inspect needle cover	
		<ul> <li>Avoid touching the needle cover itself; handle it by the connected tubing to the base</li> </ul>	Errors		Inspection of tubing omitted	Inspect tubing	
Pass filling needle to operator B – No T&O of critical surfaces	8.3	Pass covered filling needle over filling train to operator B <ul> <li>Ensure operator B is ready for transfer</li> <li>Go slow and carefully nick up the needle by the base</li> </ul>		_	Remove needle cover prior passing to operator B	Reject the filling need	le 🗆
		<ul> <li>Ensure that the needle is securely held tip facing up</li> <li>Pass the needle through a safe path without T&amp;O of critical surfaces in the middle of the filling train</li> </ul>	Errors		Critical surfaces of filling station overreached	Document and report supervisor	to 🗆
Pictures - critical p	oints						Frames
	Insp	ect the needle cover integrity and placement.	filling need	die sie	eve and pass it without T&O need	rator B	8.1 8.2 8.3





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	<ul> <li>Assembling a team of design overall design and schedule</li> </ul>
	showed the use of BIM can
	TRADITIONAL DELIVERY
	Design
	ONEsolution <sup>™</sup> DELIVERY
	Design Early Packages Const
	Continuous Verifica
$\left( \right)$	
	<ul> <li>Principal: Personnel should be a visual in the second secon</li></ul>
	Processes and monitoring s
	<ul> <li>Understanding how we will</li> </ul>
	VR training on aseptic tech stepping near equipment for
	Con
	- Droduct quality, operational
	<ul> <li>Product quality, operational determined by any single p</li> </ul>
	principles that collectively r
	regulators tomorrow and ov

![](_page_0_Picture_38.jpeg)

# **Design Build and BIM Process**

gn build partners that have the same integrated approach to the project goals leads to the best e to market. This allows for us to bring in experts from every field to achieve our goals. The results cut time by 50% faster and reduce costs.

![](_page_0_Figure_41.jpeg)

### **Team Is From Start to End**

Id have adequate qualifications and experience, training, and behavior with a specific focus on he protection of sterile product during the manufacturing, packaging, and distribution processes. systems for sterile product manufacture should be designed, commissioned, qualified, monitored, personnel with appropriate process, engineering, and microbiological knowledge. (Annex 1) Il train our teams to run the facility while in operations is part of the overall project plan. Using nnique to machinal timing models to ensure our operators have the proper technique before ever or qualification.

![](_page_0_Picture_44.jpeg)

![](_page_0_Picture_45.jpeg)

### clusion

al efficiency, and compliance isn't process or design element. These intained through holistic design meet the need of the market and over the horizon.

## References

- Comparison of Conventional Cleanrooms, Restricted Access Barrier Systems, and Isolators. Diplomarbeit zur Erlangung des akademischen Grades Master of Science in Engineering. Der Fachhochschule Campus Wien Master-Studiengang Biotechnologisches Qualitätsmanagement
- <sup>2</sup> July/August 2019. The Digital Twin: Creating Efficiencies in a Virtual World. Andrew Whytock.
- <sup>3</sup> Effect of Building Information Modeling (BIM) on reduced construction time-costs: a case study Moh Nur Sholeh1\*, Shifa Fauziyah1, Riqi Radian Khasani2
- <sup>4</sup> Civil and Planning Department, Vocational School, Diponegoro University, Semarang 50275, Indonesia.
- <sup>5</sup> Civil Department, Faculty of Engineering, Diponegoro University, Semarang 50275, Indonesi.