

PROS & CONS OF MOBILE PCS IN A PRODUCTION ENVIRONMENT

Sam Russem Jan Thriene ISPE Product Show Track 4, Session 4 September 26, 2018





Speaker Biography

Jan Thriene, Business Development Manager Systec & Solutions

Jan Thriene is the Business Development Manager at Systec & Solutions, a Karlsruhe, Germany based manufacture of best in class GMP-IT hardware for clean room production environments.

Mr. Thriene has over 7 years' experience providing HMI solutions in the pharmaceutical, food and cosmetics industries. Prior to his work with Systec & Solutions, Mr. Thriene held management roles in China and throughout Europe for various American firms.





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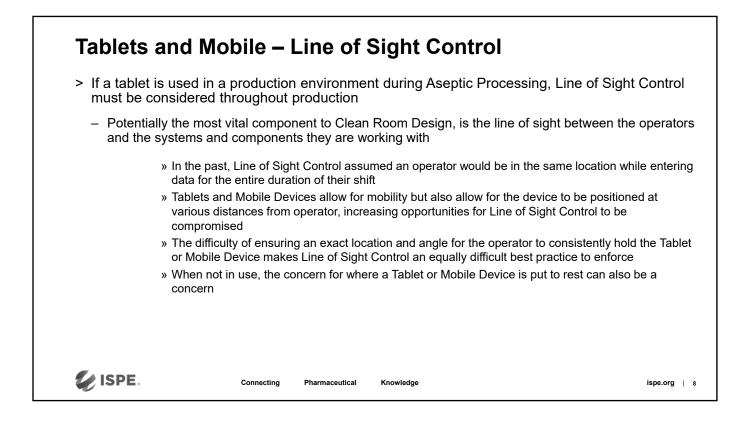
Knowledge



Tablets and Mobile - Regulatory

- > Tablets (and somewhat mobile trolleys) are reliant on battery power and wireless LAN
- > Additional controls may be needed for regulatory compliance
 - ICH Q7 Section 5.4
 - » 5.43 "There should be controls to prevent omissions in data (e.g., system turned off and data not captured)"
 - » 5.48 "If system breakdowns or failures would result in the permanent loss of records, a back-up system should be provided"
 - FDA Draft Guidance "Data Integrity and Compliance with cGMP" April 2016
 - » Must document or save data at the time of performance to create a record in compliance with cGMP requirements
- > Loss of Wi-Fi signal or a dead battery can lead to data integrity issues

> If a table data inte	t leverages mobile OS, additional concerns arise regarding security, confidentiality an grity
	uidance "Use of Electronic Records and Electronic Signatures in Clinical Investigations Unde R Part 11 – Q and A" – June 2017
	» Access Controls must be as per any other kind of regulated computer system
	» All regulated data must be traceable to its origin: the user or the mobile device itself
	» Additional checks are required such as a "heart beat" to ensure continuous device connectivity
	» Data is considered "source data" only when recorded in a permanent manner, not in mobile devic memory or temporarily resident in a vendor's cloud
	 Encryption, digital signatures and/or biometrics required in "open systems" as classified by 21 CFR Part 11
	» For mobile devices, disabling "remote wiping", restricting the installation of certain apps, disabling automatic updates, and removing sensitive data prior to re-allocating the device should be implemented
	» Additional validation to ensure the mobile device reliably transmits data to permanent storage system
	» Additional personnel training on mobile technologies may be required



About Us

Systec & Solutions GmbH

- > Experts for GMP-IT hardware solutions
- > Fully mobile or fix installed HMI solutions for clean rooms and hygienic areas
- > Full service offering around standard & customer specific products and solutions
- > Products used for MES, DCS, OEE, KPI and environmental monitoring applications
- > Globally used by Pharmaceutical, Biotech, F&B and Cosmetics industry
- > Applied by 15 out of the 20 largest Pharma companies worldwide
- > Based in Karlsruhe, Germany
- > DIN ISO 9001:2015 certified



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About Us

Grantek Systems Integration

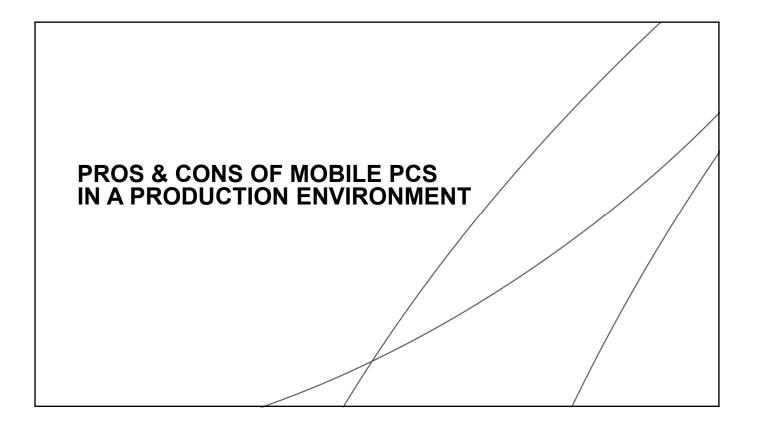
- > Systems Integrator and Business Solution Provider
- > From the plant floor to the boardroom
- > Founded in 1980
- > 200 professionals across 17 Global offices
- > Serves the North American Pharma and Life Sciences industries
- > Member of CSIA (Control System Integrators Association)
- > Solution provider in Smart Manufacturing, Industrial Networking, Automation and Industrial Safety

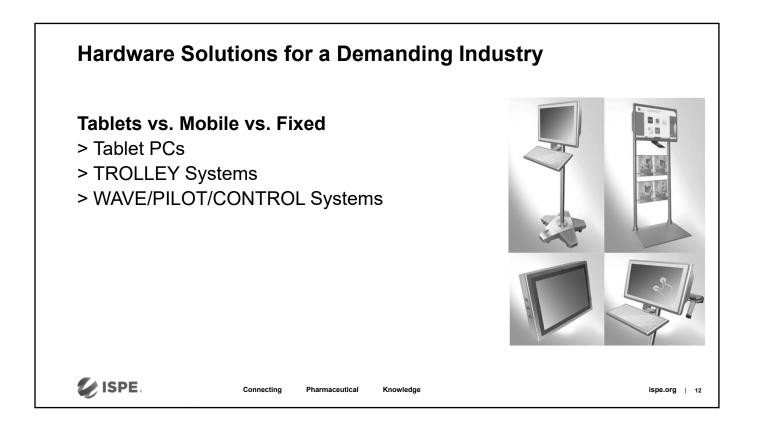




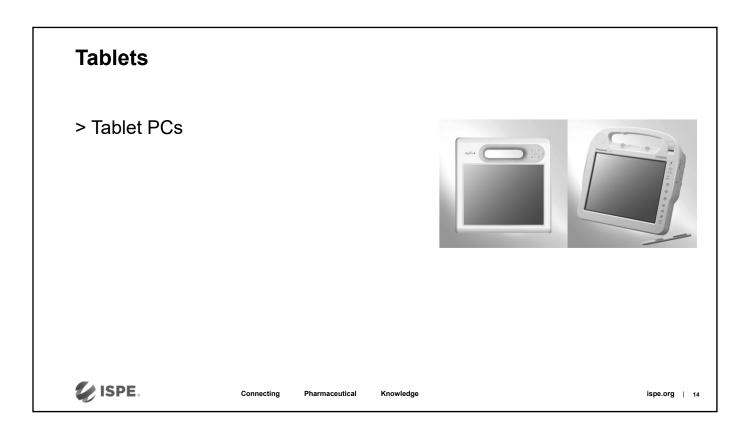
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Customer Deci	sion B	ased Or	ו:	
> Cost 💼 > Handling 🎾 > Design 🖨				
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Capex is low, Ta	ablet PCs are u	usually cheap	
Opex is high, Ta	ablet PCs are s	short lived	
-p			
	ADVANTAGE	DISADVANTAGE	
	ADVANTAGE Low Capex	DISADVANTAGE High Opex/Maintenance Cost	
		High Opex/Maintenance Cost	
		High Opex/Maintenance Cost Short Product Life Cycle	

Tablets - Handling ≽

Easy to move from Point to Point, excellent mobility

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Easy to drop, but easy to replace

Battery powered solution only, severely limited usability during recharge Must be carried by the operator for extended period of time

ADVANTAGE	DISADVANTAGE
High Mobility	Battery Operated
Lightweight	On Screen Keyboard
Easily Replaced	Weight During Operation

	astic surfaces, ope	ns, adopted to industrial use en interface connectors	
Can be adopt	ed to GMP require	ements, but with limitations	
	ADVANTAGE	DISADVANTAGE	
	ADVANTAGE Many Interfaces	DISADVANTAGE Difficult to Clean	
		Difficult to Clean	
		Difficult to Clean Cleaning Agents too Aggressive	

Γ



noneys - C	Cost 🛋		
	n, designed for pharma requ industrial grade components		
	ADVANTAGE	DISADVANTAGE	
	Low Opex	High Capex	
	· ·	5 - 1	
	Industrial Grade Components	Maintenance Required	

Trolleys - Handling 🍃

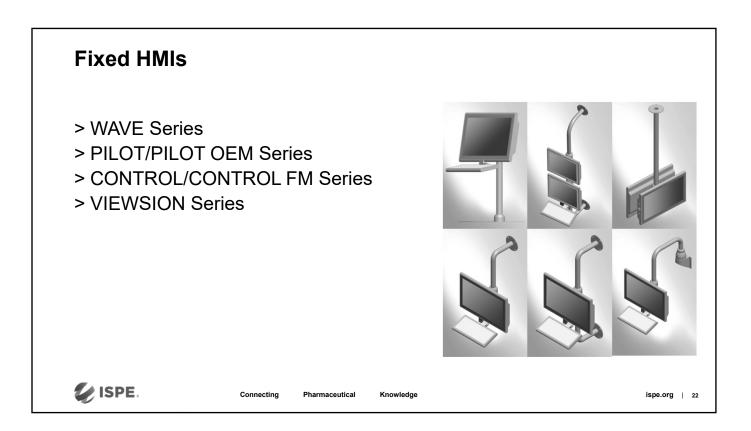
Easy to move from Point to Point Battery or AC powered solution Useable during recharge

ADVANTAGE	DISADVANTAGE
High Mobility	"Parking Space" Required
Battery and Mains Powered	Maintenance on Wheels and Battery Required
Inductive Charging Available	Potentially Large Surface to Clean
Full Keyboard and Touchpad	
Large Screen Size with Multi Touch	

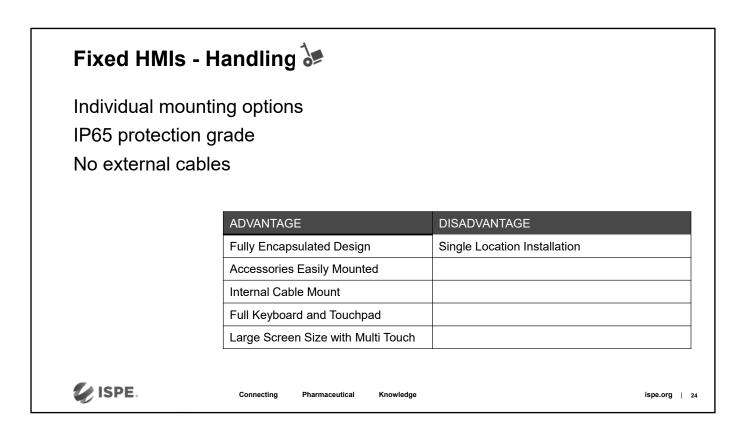
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Fully encaps	e in pharma/clean room applications sulated design		
No issues w	ith common cleaning agents		
WLAN or LA	N connection		
	ADVANTAGE	DISADVANTAGE	
	ADVANTAGE Easy to Clean	DISADVANTAGE	
		DISADVANTAGE	
	Easy to Clean	DISADVANTAGE	



Capex is mod	erate oharma requirements		
•	st non-existent, industrial grade	e components	
-	-		
	ADVANTAGE	DISADVANTAGE	
	ADVANTAGE Very Low Opex	DISADVANTAGE Moderate Capex	



Fixed HMIs	- Design 🧬	
Fully encapsu	in pharma/clean room applicatio Ilated design h common cleaning agents	ons
	ADVANTAGE	DISADVANTAGE
	ADVANTAGE Easy to Clean	DISADVANTAGE Limited Design Flexibility
	Easy to Clean	Limited Design Flexibility



Tablet

Tablet allows for independent and mobile use and can store and access information.

Tablet is not well suited for applications where you need to operate continuously.

Tablet is best suited for application where a limited amount of data needs to be displayed for a limited period of time with limited interaction.

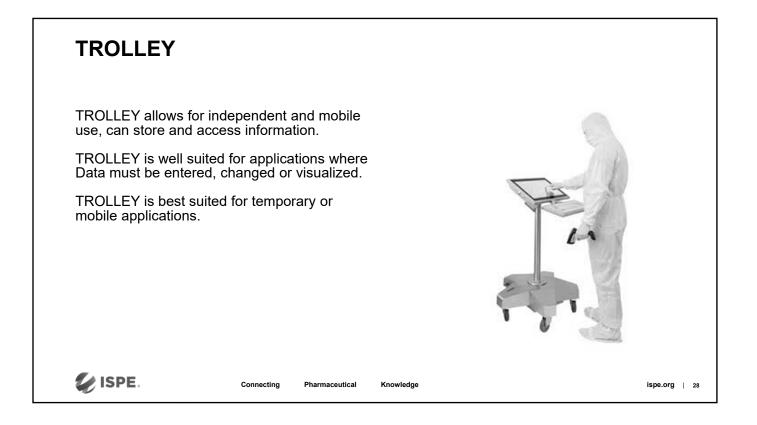


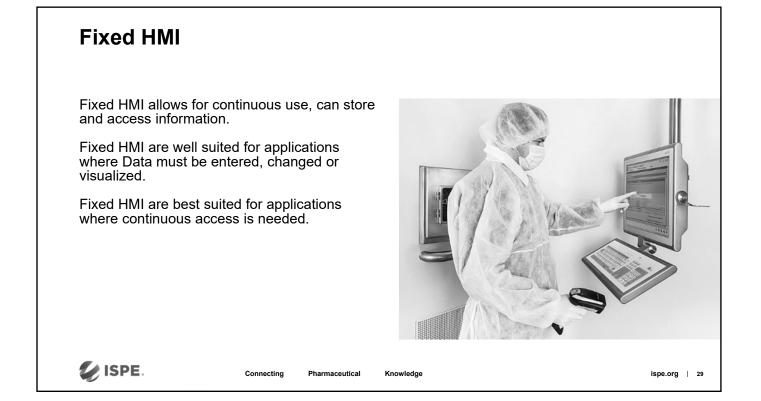
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APPLICATIONS	TABL	ET PC TROLL	EY FIXED HMI
DCS Visualization			
MES Visualization			
ERP System			
Paperless Documentation			
Batch/Track & Trace			

