Implementing a Manufacturing Execution System (MES) Project

PharmOut
Regulatory Knowledge, Practically Applied.

Hosted by PharmOut

GMP FORUM

Implementing a Manufacturing Execution System (MES) Project

Agenda

1) Plan early, plan well
2) Review all processing steps early in your MES project
3) MES will flow better if well prepared

PharmOut WAYAHEAD SYSTEMS

MES – Existing systems

Different systems used at a typical manufacturing site:

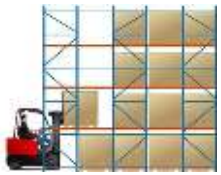
ERP (SAP, JDE, Ostendo, Navision, MS Dynamics, etc)

Weigh & Dispense (3WS)

PLC (Rockwell, AZO, Siemens, etc)

Document Management

Laboratory Systems



Warehouse Management

PharmCut WAYAHEAD SYSTEMS

MES – Existing machines used onsite

Machines used at a typical manufacturing site:

Blender / Mixer
(Servo-Lift, Matcon, etc)

Tablet Compression
(Korsch, Sejong, etc)

Coating (Thomas,
Diosna, etc)

Bulk bags

Filing

Packaging

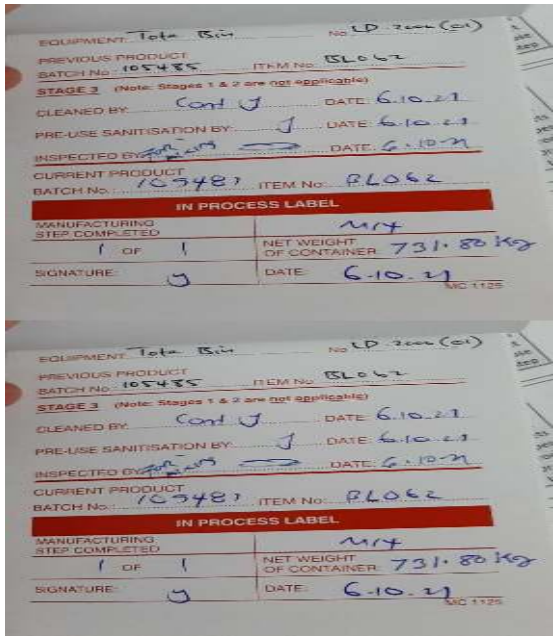
PharmCut WAYAHEAD SYSTEMS

MES – Equipment used onsite

Equipment used at a typical manufacturing site:

- Tools (Sieves, tooling, clamps, etc)
- Containers (Tanks, IBC, plastic buckets, etc)
- Machines (Blender, Compression, Coating, Filling, etc)
- Testing devices (Erweka, Bruker, etc)
- Rooms (Weighing, Granulation, Coating, Packing, etc)

Tote Bin Cleaning Card



PharmCut WAYAHEAD SYSTEMS

MES Activities – recording in-process test results

Testing devices used at a typical manufacturing site:

- Tablet tester (Erweka, Ischi, etc)
- Near Infra Red (NIR) checker (Bruker, Thermo Fisher, etc)
- HVAC (Johnson Controls, etc)

PharmCut WAYAHEAD SYSTEMS

MES requires interaction between systems, machines & equipment

ERP

W/D

MES

Blenders | Compression | Coating

Machines | Devices | Containers | Tanks | Sieves / Tooling | Rooms

Tablet Testers | NIR checking | HVAC – Temp and RH checking

PharmCut

WAYAHEAD SYSTEMS

MES Considerations

Project issues – Legacy systems

- Original vendor no longer available to support the legacy system
- Interface updates not possible or very expensive
- Requires data entry of this information into MES

can your legacy system work with MES?

PharmOut WAYAHEAD SYSTEMS

MES Improvements

Example Test Result

MES project delivered processing improvements

- In process control product testing results better managed
- NIR material checking results interfaced automatically
- Equipment cleaning & equipment issue to each order improved

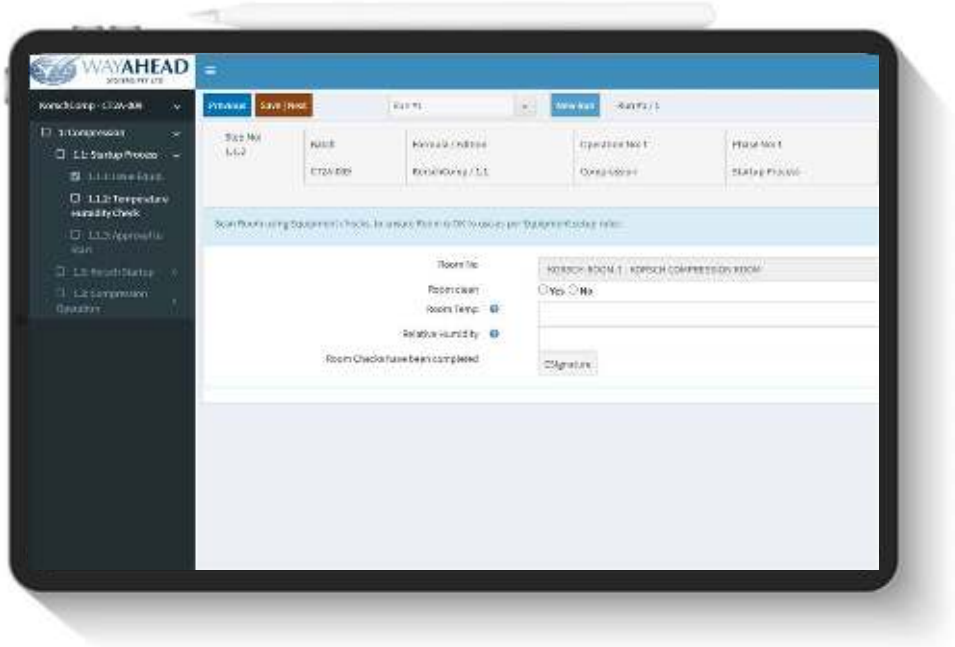
tablet test results automatically interfaced to MES

PharmCut

WAYAHEAD SYSTEMS

MES Hardware

- Tablet device is usually the best screen during MES actvities
- A weighing room uses a PC screen, electronic balance & barcode scanner
- The screen on the right shows a typical MES Menu structure
- Tablet device displays the menu structure on LHS (in black)
- Tablet device displays data entry activity on RHS
- Different data entry options are available depending on the activity

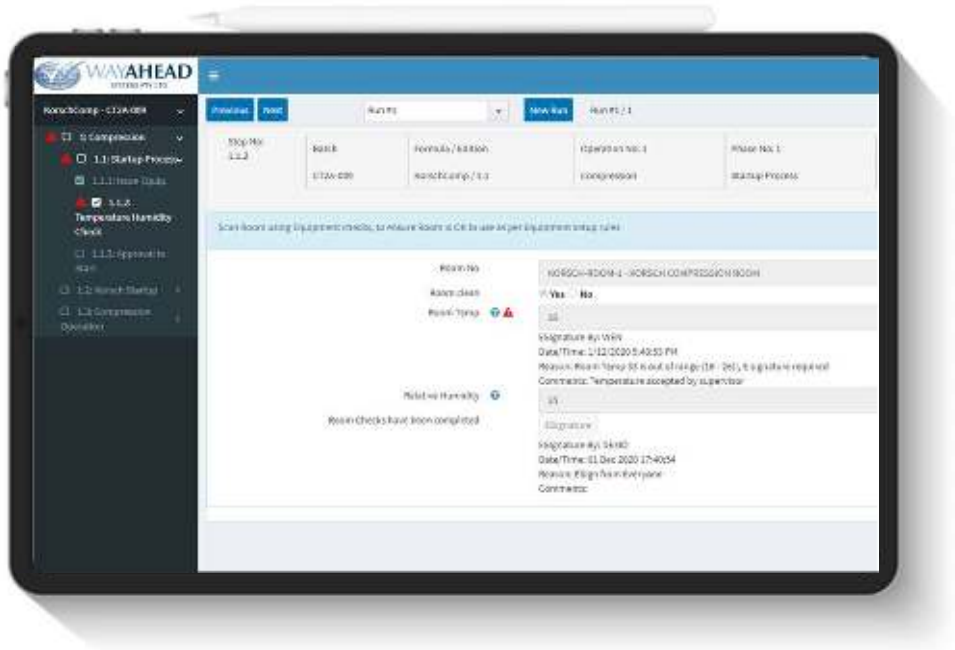


different data entry uses flexible screen layout in MES

PharmCut WAYAHEAD SYSTEMS

MES – error management

- Tablet device displays the error message
- If necessary an eSignature is required to acknowledge the error
- Error is highlighted on the black menu on LHS & also on EBR

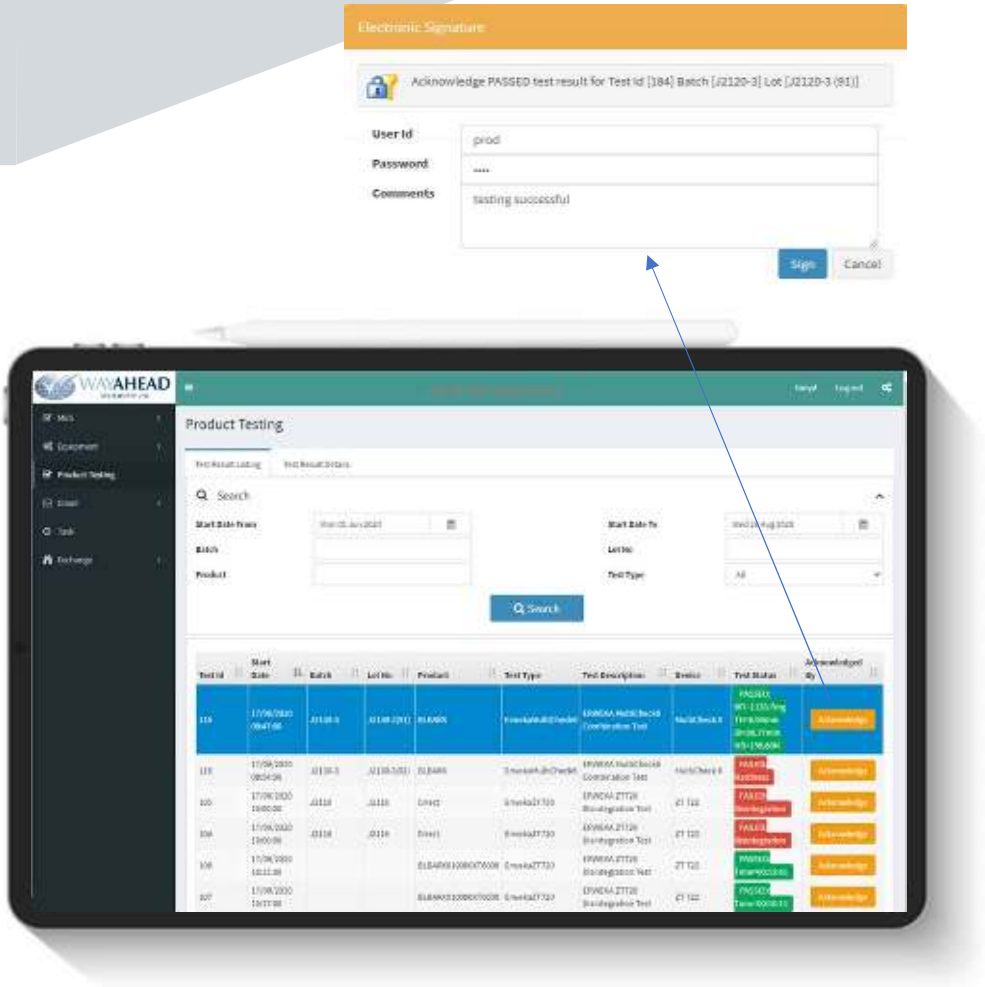


Data entry errors are immediately highlighted

Any error will be recorded within MES

PharmCut WAYAHEAD SYSTEMS

MES – in-process control test results occur in many phases



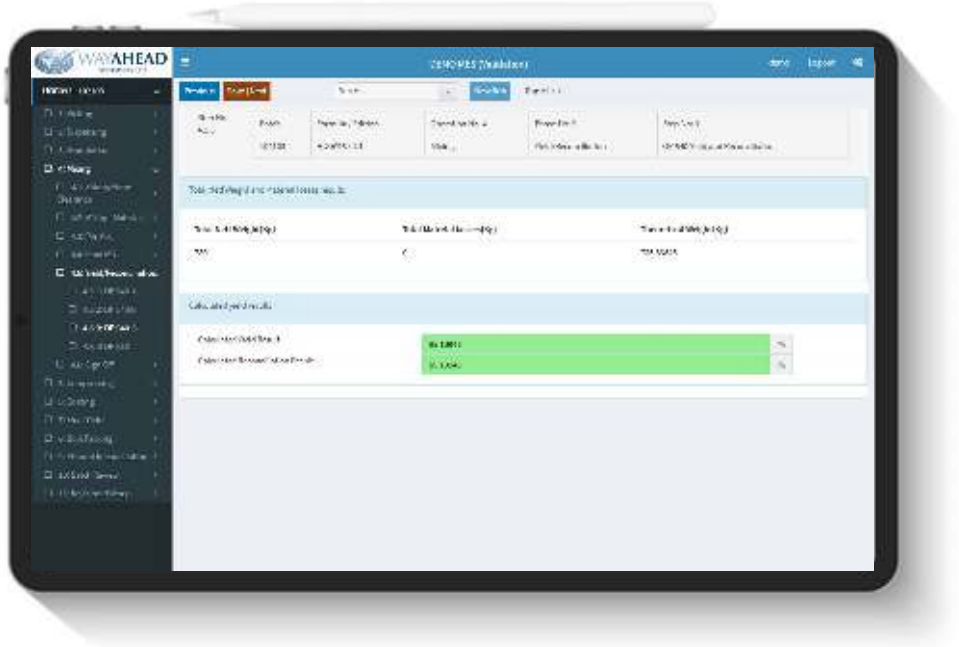
In-process-control (IPC) results are recorded and transferred automatically to MES

- An operator completes IPC tablet or liquid testing
- The results data is then automatically interfaced to MES
- Additional MES limits checks can be tested, optionally
- Final test results are recorded & optionally acknowledged in MES
- Container which the IPC results are for – can be automatically approved

PharmCut WAYAHEAD SYSTEMS

MES – reconciliation of actual with yield calculation checks

- An operator records what is occurring during an MES
- At the end of the MES process, the final Yield is checked
- If the Yield is not within expected tolerance range – an error is displayed
- If the Yield is OK, system is updated
- All reconciliation data & yield results are included in MES EBR report



Various reconciliation checks can be setup

Warnings highlighted when outside expected range

eSignatures required to accept final yield details

PharmOut WAYAHEAD SYSTEMS

MES Validation

- Wayahead will provide a complete Validation Protocol in Word format
- Site Quality department will review, change & approve the protocol
- IQ (Installation Qualification) manages implementation of OS, DB & MES
- OQ (Operational Qualification) manages creation of all test results
- PQ (Performance Qualification) repeats main test results in live MES system

Operation Qualification (OQ) Test Details

XYZ Pharmaceuticals

Chapter: 25 Manufacturing Execution System work instructions

Test No.:	**100**	**Confirm Order action process before dispensing.**
Description:	**Confirm Order action process before dispensing.**	
Methods:	1. Setup the formula to contain a form action to be input during Dispensing and be displayed before dispensing (DISP-B) Record the following: formula _____ itemno _____ material _____ seqno (formaction) _____ E-Signature rule _____ 2. Raise a new order in SWS which uses the same formula from method 1. Record the order _____ 3. Access the Dispensing program, select the order from method 2, and access the item/material list and highlight the itemno from method 1. 4. Press Enter to select the material and scan or enter a valid lotno. 5. Enter actual value on the Ordeaction detail screen, which is outside the upper and lower tolerance. 6. This is a negative test. Confirm that any actual value outside the upper or lower tolerance is not accepted and follows the E-Signature rules. Repeat 5 - 6 for all other negative tests. 7. Enter the actual value on the Ordeaction detail screen, which is within the tolerance. 8. This is a positive test to ensure the actual value is accepted without warnings. Confirm that any actual value within the tolerance is accepted.	
Expected Result:	1. Confirm that the formula item has a formaction record with DISP-B characteristics. Print Screen the formaction detail screen. 2. Confirm that order is created. Print Screen the Order/Item list screen to highlight the materials in this order. 3. Confirm the itemno and material the same as method 1. Print Screen the order/item list. 4. Confirm the Disp-B message with the details from the screen in method 1 is displayed. Print Screen the Order Action detail screen. Record the following: target value _____ target uom _____ lower tolerance _____ upper tolerance _____ 5. Confirm the data entered at actual value by saving a print screen of the Order action detail screen. Record the actual value _____ 6. Confirm the E-Signature rule is followed for the incorrect actual values. Print Screen the Error or Warning screen. Repeat 5 - 6 for all other negative values. 7. Confirm the data entered at actual value by saving a print screen of the Order action detail screen. Record the actual value _____ 8. Confirm the actual value is accepted. Processing continues to the weighing screens. Print Screen the following weighing screen.	
Actual Result:		
Tested By:	**Date:** / /	**Reviewed By:** **Date:** / / **Ref:** **Pass:** ☐ **Fail:** ☐

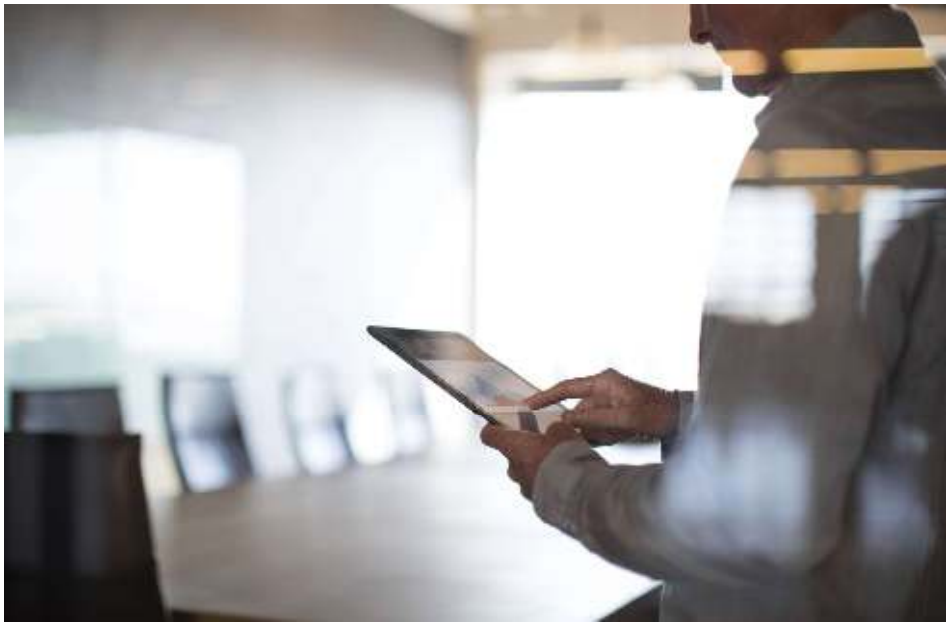
PharmCut WAYAHEAD SYSTEMS

Conclusion

- Error checking is recorded
- Event management of defects is available
- Quality Approval at completion is included
- Electronic batch record (EBR) can be captured
- Automatic approval of IPC tested tablets is possible
- Full audit trail of eSignatures is recorded for all warnings
- Automatic interfaces eliminate many data entry activities
- MES can improve many aspects of your current procedures

Reminder on project planning

1) Plan early, plan well
2) Review all processing steps early in your MES project – this is critical
3) Your project will flow better if well prepared and all interfaces are ready BEFORE the equipment is used onsite



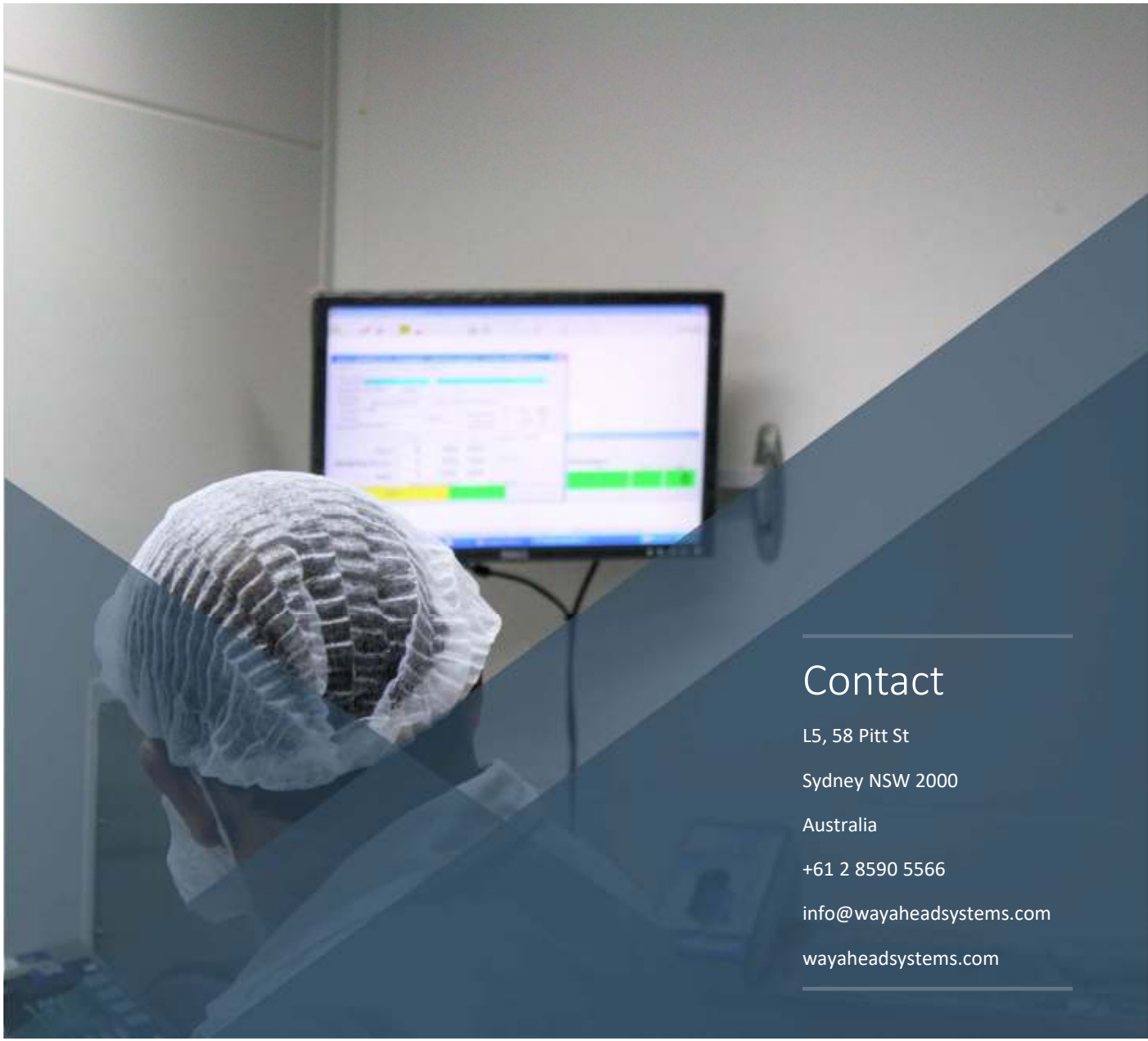
PharmOut WAYAHEAD SYSTEMS

THANK YOU

John.Nesbitt@WayaheadSystems.com

+61 412 565 829

WAYAHEAD SYSTEMS



Contact

L5, 58 Pitt St

Sydney NSW 2000

Australia

+61 2 8590 5566

info@wayaheadsystems.com

wayaheadsystems.com