

Piloting Job Instructions in a GMP regulated environment



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Agenda

- 1 Introduction to Novo Nordisk
- 2 Job Instructions – where to start?
- 3 From pilot to global roll out



Novo Nordisk at a glance



<p>PRODUCTS MARKETING IN 180 COUNTRIES</p>  <p>DIABETES</p>	<p>AFFILIATES IN COUNTRIES 75</p>  <p>R&D CENTRES IN CHINA, DENMARK, INDIA AND US</p>	 <p>OBSESITY</p>	<h3>Novo Nordisk and Product Supply</h3> <ul style="list-style-type: none"> • Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care • Novo Nordisk also help people defeat other serious chronic conditions as haemophilia, growth disorders and obesity • Product Supply is responsible for the supply of all marketed and phase III development products within the treatments of: <ul style="list-style-type: none"> • Diabetes • Haemophilia • Growth disorders • Menopause • Obesity 
<p>STRATEGIC PRODUCTION SITES IN BRAZIL, CHINA, DENMARK, FRANCE AND US</p>	 <p>EMPLOYS APPROXIMATELY 42,300 PEOPLE</p>	<p>DKK 107.9 BILLION IN TOTAL REVENUE</p>	
 <p>HAEMOPHILIA</p>	<p>SUPPLIER OF MORE THAN HALF OF THE WORLD'S INSULIN</p>	 <p>230,000 SHAREHOLDERS</p>	
<p>26,800,000 PEOPLE USE OUR PRODUCTS</p>			

Product Supply

Supplies products for all therapeutic areas



CARL LYONS
Carl lives in Denmark and has haemophilia A

Haemophilia





JIM SHEEDER
Jim has type 2 diabetes and lives in the US

Diabetes





TRINITY ALFARO
Trinity lives in the US and has type 1 diabetes

Hormone Replacement Therapy





CONNER AND JO
Conner and Jo both live with a growth disorder

~4,000
PRODUCT VARIANTS

Growth hormone disorders





EVE BROUTY
Eve lives in the US and has a BMI of 38

14.200 EMPLOYEES
GLOBALLY

Obesity



12 PRODUCTION SITES
WORLDWIDE

Product Supply

A global network divided into different areas





DFP Hillerød (DK)



DFP Kalundborg (DK)



DFP Bagsværd (DK)



DFP Chartres (FR)



DFP Montes Claros (BR)



DFP Clayton (US)



DFP Tianjin (CN)



ERIK NIELSEN SCHMIDT AND LASSE BO LUMHOLDT-RIISAGER
Director and chemist at site Kalundborg
Denmark

Diabetes Finished Products

Employees

- ~ 6.230

Locations

- Denmark (Hillerød, Kalundborg and Bagsværd)
- France (Chartres)
- Brazil (Montes Claros)
- USA (Clayton)
- China (Tianjin)

Processes

Diabetes Finished Products



```
graph LR; A[Formulation] --> B[Filling]; B --> C[Assembly]; C --> D[Packaging]
```



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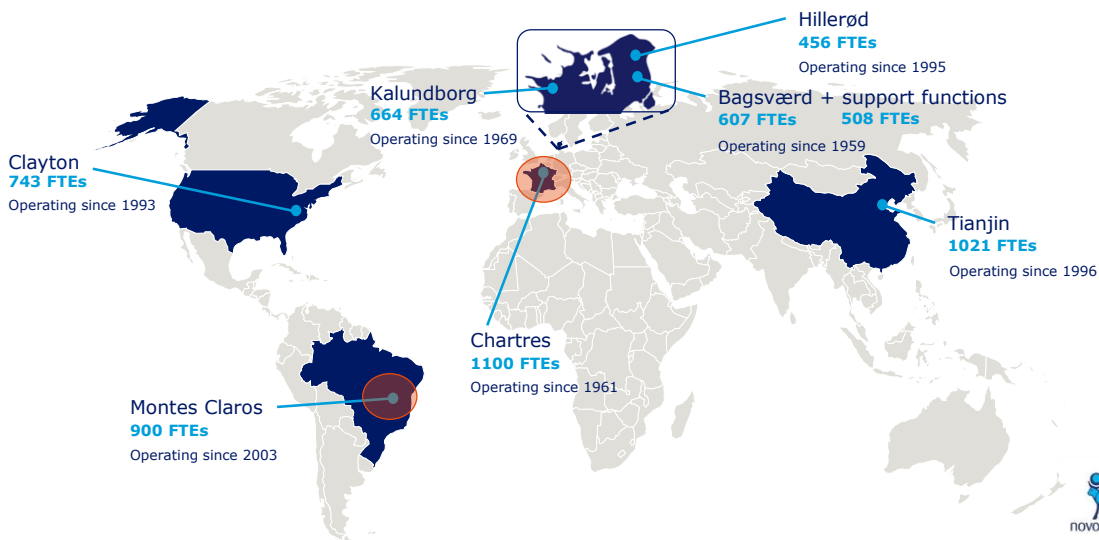


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How to start implementing Job Instructions?



Job Instructions DFP Pilots

27-04-2016

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Scoping the pilot projects. Where to write Job Instructions

Area:
Process:



FP
FlexPen Assembly
A3-A4 **Line Clearance**



AP
Env. Monitoring
Green Zone **Gowning**

of Job Instructions:
of Operators:
of SOPs impacted:

10
40
2

8
400
5






novo nordisk®

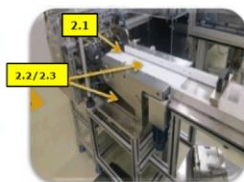
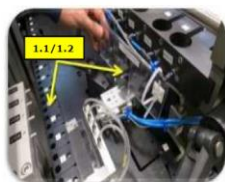
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The dimensions of a Job Instruction in our GMP context (1/2)

Passo	O que (Passos importantes)	Símbolo	Como (pontos chaves)	Por quê
1	Limpe o Held module e a corrente de Penfil		1.1 Remover Penfil, fragmentos de Penfil e componentes. 1.2 Se houver insulina, limpar com álcool e manta.	1.1.1 Para que não fiquem materiais do lote finalizado. 1.2.1 Para que não fique resíduo de insulina no equipamento.
2	Limpe a esteira de alimentação		2.1 Remover Penfil da parte superior. 2.2 Aspirar fragmentos de Penfil abaixo da esteira. 2.3 Se houver insulina, limpar com álcool e manta.	2.1.1 Para evitar mistura entre lotes. 2.2.1 Para evitar que os fragmentos lesionem o funcionamento. 2.3.1 Para que não fique resíduo de insulina no equipamento.
3	Limpe a caixa do sistema de visão		3.1 Remover Penfil e/ou componentes do interior e arredores.	3.1.1 Para que não fiquem materiais do lote finalizado.



A 3-fold document:

1. Instruction (SOP)
2. Training Material
3. Process Confirmation tool






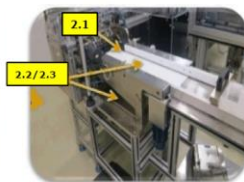
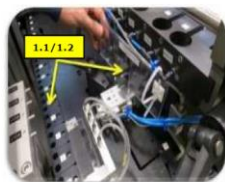
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The dimensions of a Job Instruction in our GMP context (2/2)

Passo	O que (Passos importantes)	Símbolo	Como (pontos chaves)	Por quê
1	Limpe o Held module e a corrente de Penfil		1.1 Remover Penfil, fragmentos de Penfil e componentes. 1.2 Se houver insulina, limpar com álcool e manta.	1.1.1 Para que não fiquem materiais do lote finalizado. 1.2.1 Para que não fique resíduo de insulina no equipamento.
2	Limpe a esteira de alimentação		2.1 Remover Penfil da parte superior. 2.2 Aspirar fragmentos de Penfil abaixo da esteira. 2.3 Se houver insulina, limpar com álcool e manta.	2.1.1 Para evitar mistura entre lotes. 2.2.1 Para evitar que os fragmentos lesionem o funcionamento. 2.3.1 Para que não fique resíduo de insulina no equipamento.
3	Limpe a caixa do sistema de visão		3.1 Remover Penfil e/ou componentes do interior e arredores.	3.1.1 Para que não fiquem materiais do lote finalizado.



3 systems to ensure sustainability:

1. Continuous Improvement
2. Quick Updates
3. Process Confirmation

A Change Management task

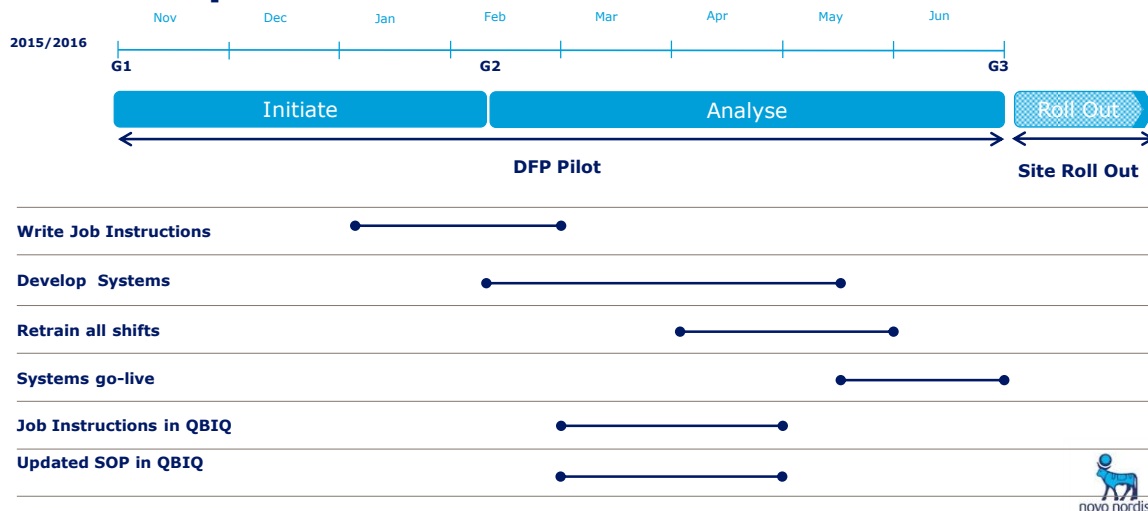


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A parallel and common implementation method for both pilots



Job Instructions DFP Pilots

27-04-2016 slide no 14

Job Instructions Pilots – main take aways



DFP MOC & CH
JOB INSTRUCTION
PILOT

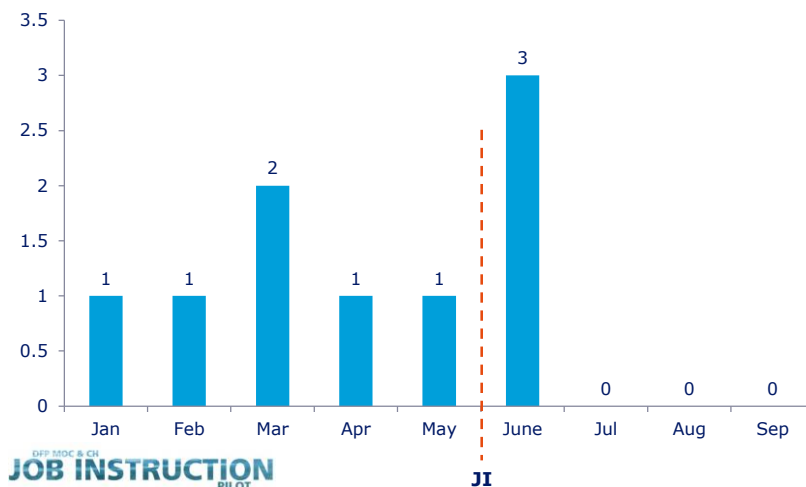


And finally... the results Site Montes Claros, Brazil

Job Instructions DFP Pilots

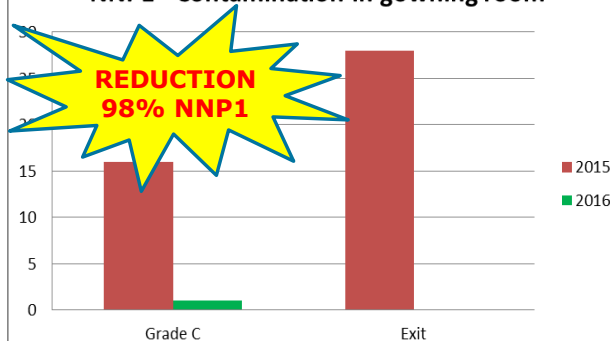
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Deviations in line clearance operations

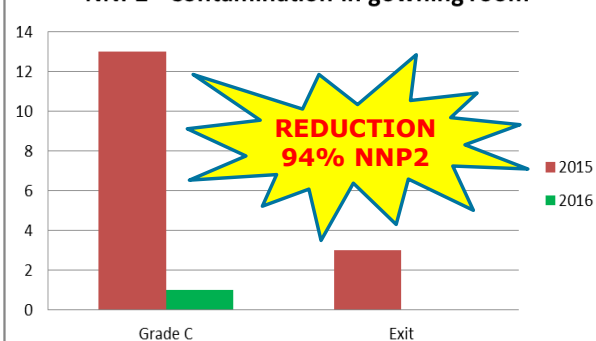


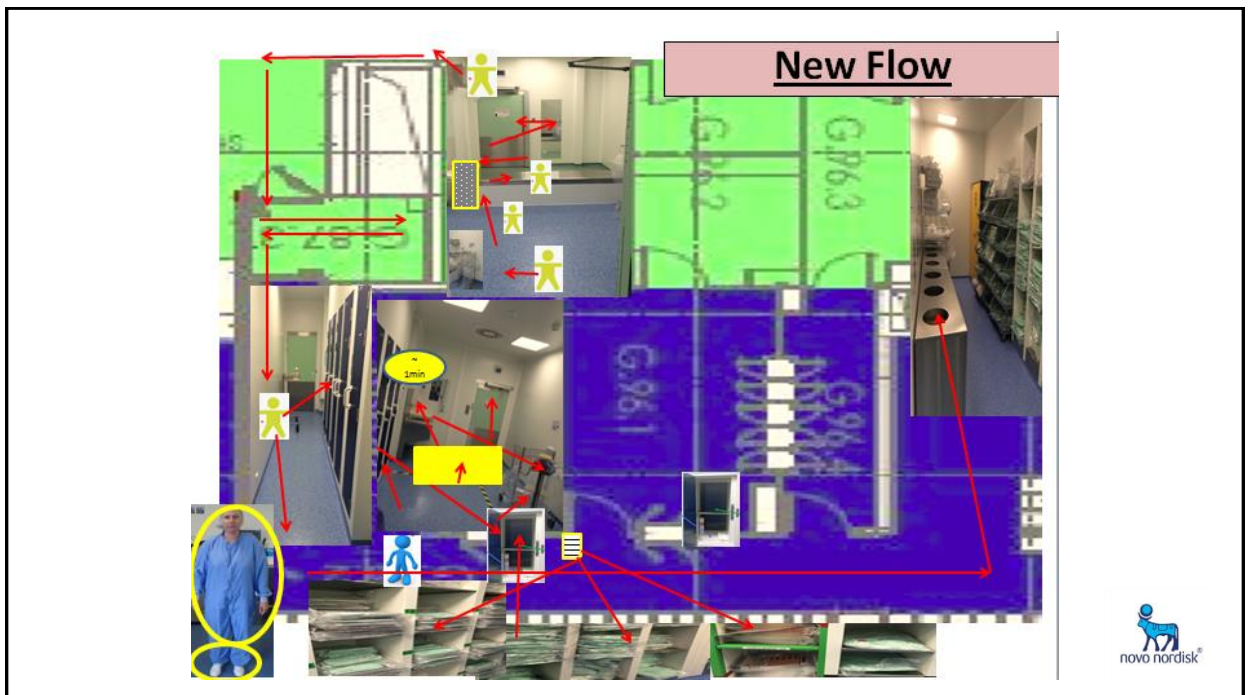
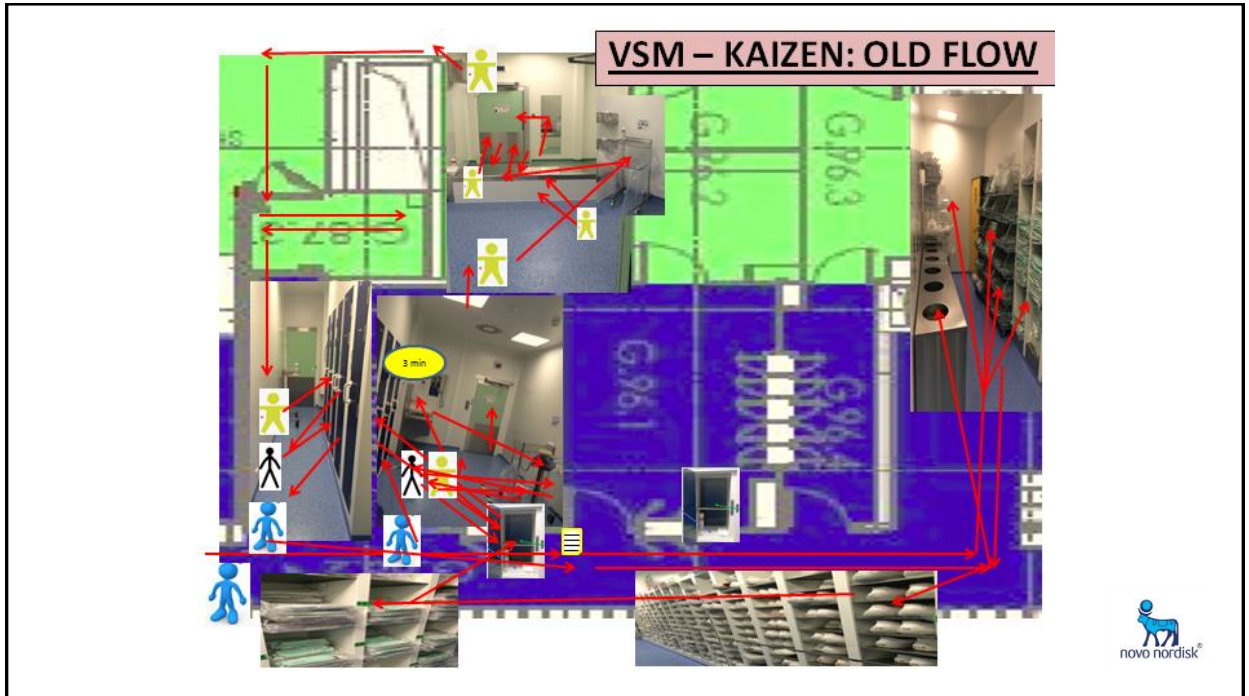
And finally... the results Site Chartres, France

NNP1 - Contamination in gowning room



NNP2 - Contamination in gowning room





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- ③ From pilot to global roll out



Broad commitment to implement Job Instructions in new production sites and areas

Pilot Wave **Start 2H 2016** **2017 and beyond**

- | | | |
|-----------------|-----------------|--------------|
| ✓ Chartres | • Chartres | • Kalundborg |
| ✓ Montes Claros | • Montes Claros | • Clayton |
| | • Bagsværd | |
| | • Tianjin | |
| | • Hillerød | |
| | • APX | |



Documenting pilot learnings. The Job Instruction Implementation Standard

Training in JI
writing

Write 1st draft

x5 Tests

Final draft

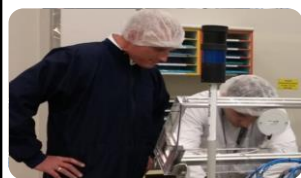


4P training with
JI

Improvement
Ideas

JI Process
Confirmation

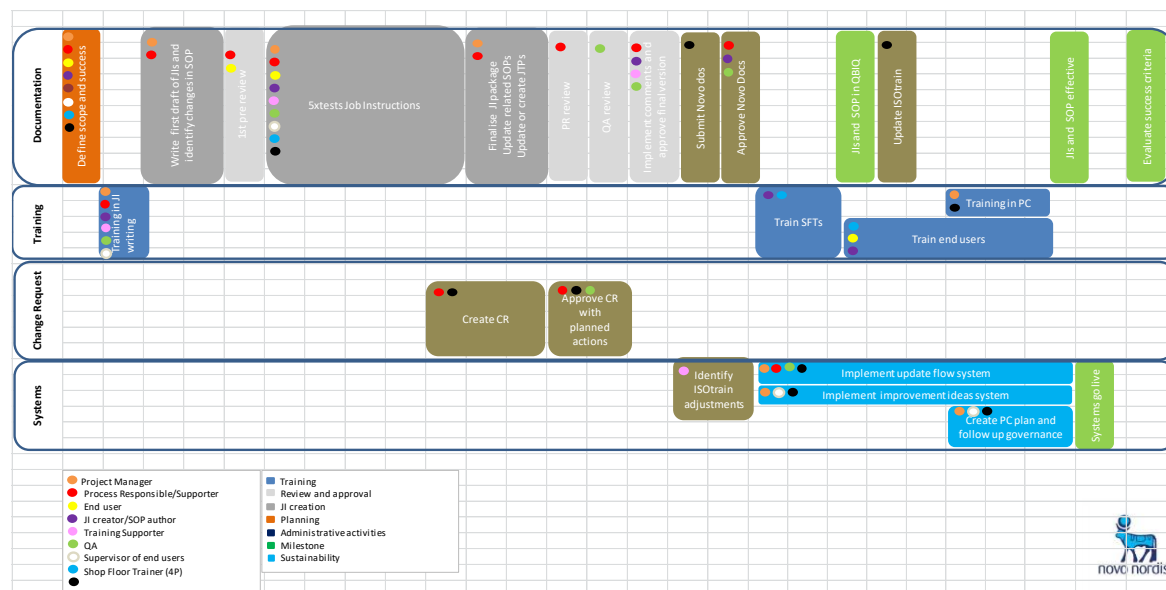
Review process



Flow for updating JIs



Standard for implementing Job Instructions – Step by Step



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The process to build central support to the global roll out of Job Instructions

