



# Using SQC PI Analysis to reduce number of exceptions with a results in lower cost of quality

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**Abbott**

# Agenda

- About Abbott Nutrition
- Process Monitoring and Control - Global Initiative
- Adopting PI as core platform
- Pouch Filling use case implementation
- Reaction Plan and standardization

# IMPROVING LIVES FOR 125+ YEARS



## **1880s**

Dr. Wallace Abbott advances the science of medications to improve accuracy and effectiveness.

## **1930s–1960s**

Expands into vitamins and, later, infant formula, marking decades of growth in nutrition.

## **1970s–1980s**

Creates the modern diagnostics industry with ground-breaking products.

## **1990s–2000s**

Sharpens its focus on medical devices, to deliver unprecedented innovation.

## **TODAY**

Abbott continues to shape new ways to bring better health to people all over the world, through diverse products and technologies.



**GETTING PEOPLE  
BACK TO DOING  
THE THINGS THEY LOVE**



Nutrition



Diagnostics



Medical devices



Branded generic  
pharmaceuticals



## Nutrition

# AMONG THE MOST TRUSTED NAMES IN NUTRITION WORLDWIDE

### PEDIATRIC

Infant Formula  
Growing Up Milk/Toddler  
Supplemental Nutrition

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### ADULT

Supplemental Nutrition &  
Healthy Snacks  
Disease-specific (Diabetes,  
Cancer, Kidney)  
Medical Foods

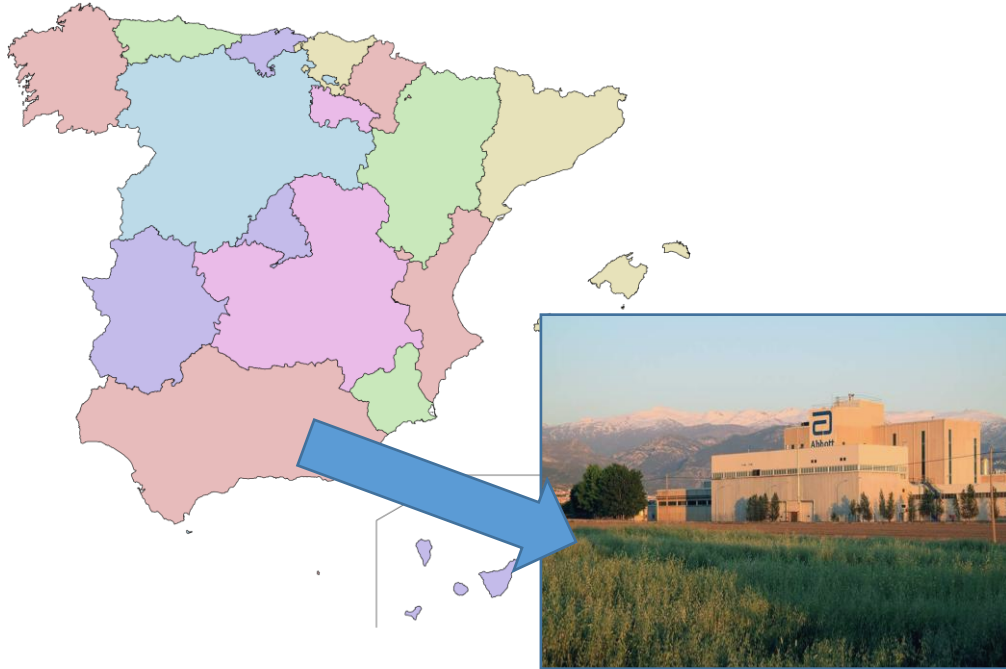
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### PERFORMANCE

Sports and Fitness Enthusiast



# Abbott Nutrition – Granada Plant



**Nutritional Powders:  
Cans, Pouches and Sachets**



# Granada Manufacturing Process



## Wet Process

Variable batch size



## Drying Process

Two driers



## Dry Blending

Nine blenders



## Packaging Process

Cans  
Pouches  
Sachets

# PMC Global Initiative: Call to the action

## Why this is important

We have detected a lack of knowledge of critical process parameters, lack of data collection and review, and poor decision making without understanding risks and impact. These all cause unintended consequences that impact our business and our brand.

## The Vision

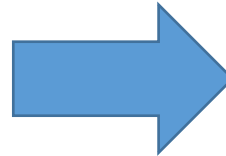
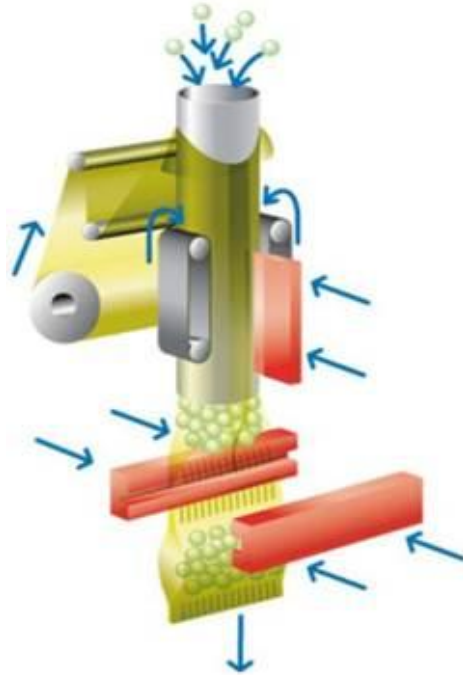
Process control is used to characterise AN products & processes and to improve capability (Cpk, Ppk) in all sites, critical TPMs & critical suppliers.

## Measures of Success

The reduction in overall variation results in lower cost of quality, reduced number of exceptions, reduced destructive testing cost, faster batch release (cycle time reduction), increased yields, rework / destructs reduction and improved customer protection.



# Granada Pouch Filling Process



# Drivers

- Better **understanding** our flexible processes.
- Identification and monitoring of the **main Critical Parameters and Attributes** helping to reduce risk of leak events.
- Support **Scrap** reduction initiatives.
- **Improved yield** on pouch line by **reducing leak** events.
- Take in control the **overfilling**.
- **Data acquisition** providing insight into the process.

# PMC & Packaging Integrity going together



## Process Monitoring and Control

- Define, Measure and Analyze Phases.
- Automatic Data Collection: Weight, Jaws temp, Oxygen Levels, leak detection system.
- PI System - Visualization
- New technology introduction

## Packaging Integrity

- Operator Standard Work
- Equipment Improvements
- New devices connecting to OPC Layer.
- Data driving the improvement and reducing variability (cpk > 1.33)

| LSL | Target | USL | LCL    | Mean   | UCL    | Cpk   | Ppk  |
|-----|--------|-----|--------|--------|--------|-------|------|
| 155 | 165    | 175 | 163,20 | 164,79 | 166,37 | 6,17  | 4,11 |
| 155 | 165    | 175 | 162,81 | 164,81 | 166,90 | 4,69  | 3,23 |
| 155 | 165    | 175 | 163,97 | 165,16 | 166,34 | 8,28  | 4,36 |
| 155 | 165    | 175 | 163,32 | 164,89 | 166,45 | 6,33  | 3,93 |
| 165 | 175    | 185 | 171,38 | 174,96 | 178,33 | 2,79  | 2,39 |
| 0   | *      | 1   | 0,241  | 0,392  | 0,544  | 4,01  | 1,93 |
| 0   | *      | 2   | 0,193  | 0,299  | 0,406  | 15,93 | 9,62 |
| *   | 20     | *   | 26,33  | 27,87  | 29,42  | NA    | NA   |
| 0   | *      | 2   | 0      | 0,177  | 0,462  | 6,39  | 2,63 |
| 0   | *      | 3   |        |        |        |       |      |
| *   | *      | 90  | 65,06  | 70,52  | 75,97  | 3,57  | 1,68 |
| 92  | 96,5   | 101 | 95,21  | 96,65  | 98,09  | 3,02  | 2,24 |

# From “paper batch record” to “e electronic data”

| Prueba | Hora     | MB    | Pa  | Comentario |
|--------|----------|-------|-----|------------|
| 1      | 08:44:58 | 508.0 | 86  | 246-47     |
| 2      | 08:48:12 | 508.3 | 80  | 367-68     |
| 3      | 09:52:31 | 509.4 | 84  | 503-62     |
| 4      | 09:50:01 | 508.3 | 81  | 800-01     |
| 5      | 09:02:09 | 506.9 | 74  | 876-77     |
| 6      | 09:08:53 | 510.0 | 84  | 1041-42    |
| 7      | 09:11:36 | 508.0 | 82  | 1207-08    |
| 8      | 09:16:03 | 506.7 | 78  | 137-75     |
| 0      | 09:17:26 | 515.0 | 126 | 1374-75    |
| 9      | 09:19:20 | 500.1 | 8   | X          |
| 10     | 09:19:55 | 500.1 | 8   | X          |
| 11     | 09:21:25 | 504.4 | 68  | -          |
| 12     | 12:32:27 | 504.9 | 63  | YACID      |
| 13     | 12:33:38 | 506.6 | 67  | YACID      |
| 14     | 12:34:47 | 505.6 | 60  | YACID      |
| 15     | 12:35:51 | 504.9 | 56  | YACID      |
| 16     | 12:37:12 | 506.4 | 66  | 1857-58 OX |
| 17     | 12:38:37 | 505.5 | 66  | 1559 OX    |
| 18     | 12:39:53 | 505.1 | 61  | 1664-65    |
| 19     | 12:41:40 | 507.9 | 68  | 1845-46    |
| 20     | 12:44:59 | 509.1 | 77  | 1941-62    |
| 21     | 12:44:59 | 509.1 | 77  | 1941-62    |

| ITEM  | UNIDAD | DESCRIPCIÓN | VALOR | UNIDAD | DESCRIPCIÓN | VALOR | UNIDAD | DESCRIPCIÓN | VALOR |
|-------|--------|-------------|-------|--------|-------------|-------|--------|-------------|-------|
| 0.15  | g      | 0.15        | 25.0  | 35     | 1.00        | 2.85  | 5.1    |             |       |
| 3.15  | g      | 0.2         | 25.0  | 35     | 1.00        | 2.85  | 5.1    |             |       |
| 6.15  | g      | 0.1         | 25.0  | 35     | 1.00        | 2.85  | 5.1    |             |       |
| 9.15  | g      | 0.1         | 25.0  | 35     | 1.00        | 2.85  | 5.1    |             |       |
| 12.15 | g      | 0.1         | 25.0  | 35     | 1.00        | 2.85  | 5.1    |             |       |
| 15.15 | g      | 0.1         | 25.0  | 35     | 1.00        | 2.85  | 5.1    |             |       |

|                  |            |
|------------------|------------|
| PESO REF :       | 400.00 g   |
| LIMITE SUP :     | 24.00 g    |
| LIMITE INF :     | 24.00 g    |
| OK LIM. SUP :    | 12.00 g    |
| OK LIM. INF :    | 12.00 g    |
| SwTng. Tara :    | 0N         |
| TARA PROGR :     | 12.65 g    |
| SOPES ACP :      | 0F         |
| ELEM TOTAL :     | 7000S      |
| CALIBRAC DINAM : | 0N         |
| Cont. TOT :      | 768586g    |
| No. Corr. :      | 768429g    |
| (OK-XCDED) :     | 29g        |
| (OR-FALT) :      | 29g        |
| CONTED EXCE :    | 39g        |
| CONTED FALT :    | 119g       |
| No Sol. Vaci :   | 09g        |
| No D-Elem :      | 149g       |
| No. Sol. Dbit :  | 89g        |
| EXT1 Cont :      | 09g        |
| EXT2 Cont :      | 09g        |
| Cont. Abselt :   | 768429g    |
| Contidad total : | 768586g    |
| PESO TOTAL :     | 30773.18kg |
| PESO MED :       | 401.85 g   |
| DISP. STD :      | 4.570 g    |
| PESO MAX :       | 706.10 g   |
| PESO MIN :       | 0.00 g     |
| RANGO :          | 706.10 g   |

Prueba de Comunicación | 18:32:57 AM | 4/19/2018

Menu de control de nivel Spec-Dec

ÚLTIMO PESO: 0.00 GRAMOS

FEEDBACK CONTROLES: APAGADO | ENCENDIDO

Peso Objetivo: 10.0g | Sobre llenado: 0.0g | Feed back: 10.0g

Limite de control inferior: 0.0g

Limite de control superior: 10.0g

Función de apagado de tolva vacía: 1

Número De Muestra: 2

Gainancia reducir peso (g): 30.0%

Gainancia añadir peso (g): 30.0%

REINICIAR PESOS | Regresar

PI Vision | RAC/Case

HOME | SACHET | POUCH | CAN | Drier 1 | Drier 2

Checkweigher Everweight: 649,6 gr (Normal)

Specification / Control Limits: 635 (Lower Control Limit), 665 (Upper Control Limit)

Statistics Summary: 10,953651,223.0003,000

Outside Control Chart

Control Chart

Check-Weigh Report

Checkweigher integration

PI Vision Visualization



# Critical Process Parameters and Critical Quality Attributes

Critical Process Parameters  
electronic data available

Oxygen Levels

Jaws Temperatures

N2 Flows

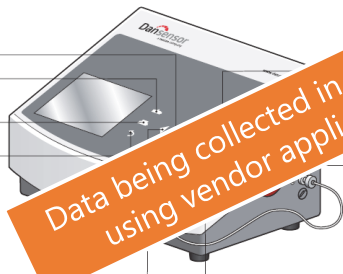
Powder related information: Bulk  
Density, flowability, Moisture

Recipe Information

Fill Weight: Every weight  
electronic data available



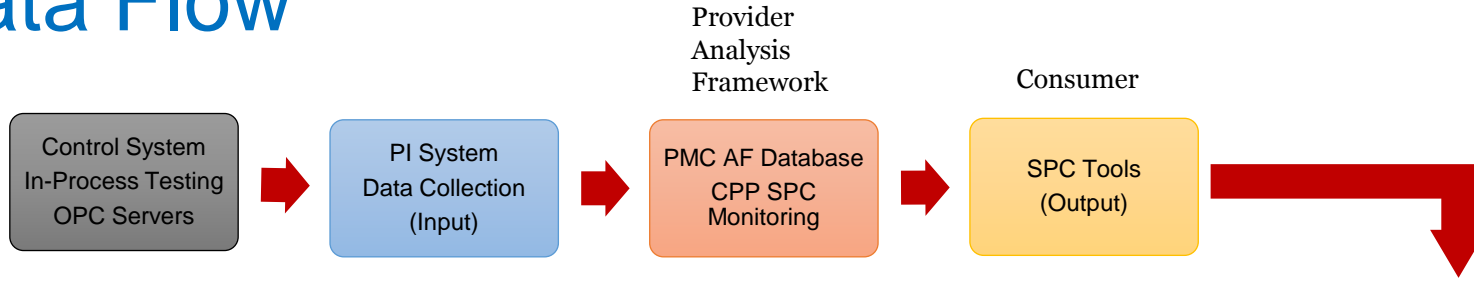
Residual Oxygen: 2 samples every  
hour



Micro Leak: At-line sampling every 5  
min. (n=2), electronic data available



# Data Flow



**Analyses**      PROS/CONS Evaluation

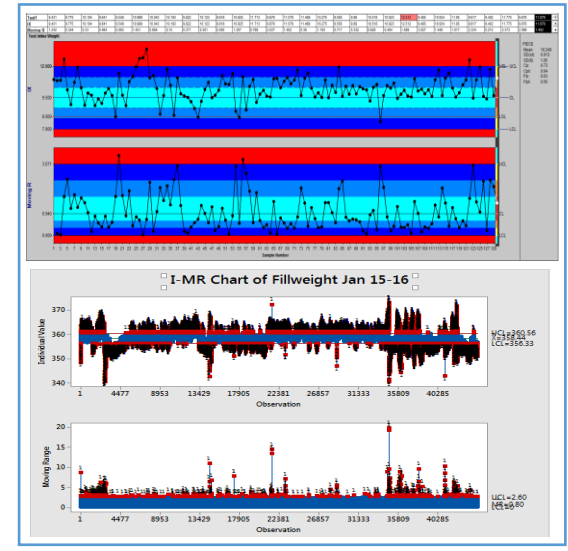
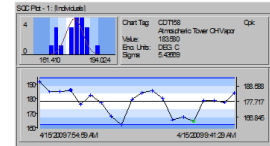
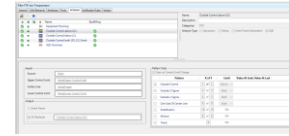
SQC pattern tests  
PI Vision

PI ProcessBook SQC

Real-time control charting



Filling room visualization



# Visualization Tools

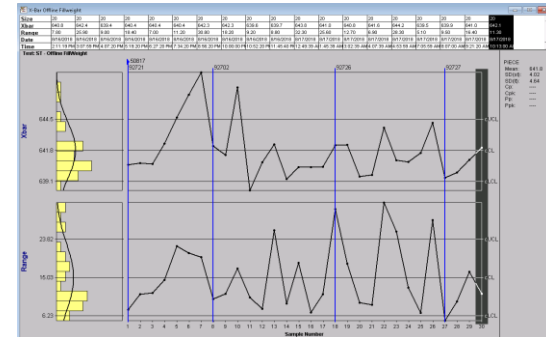
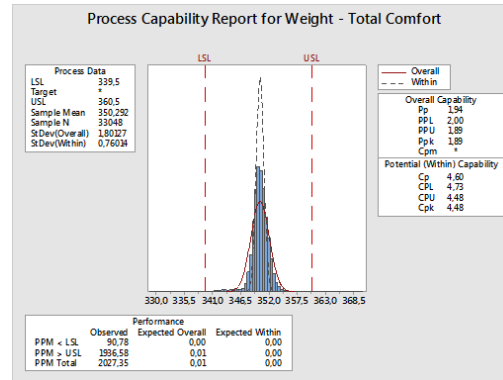
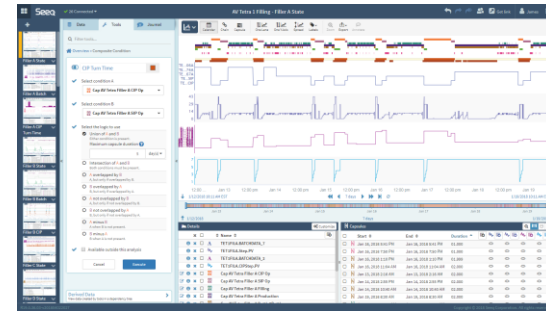
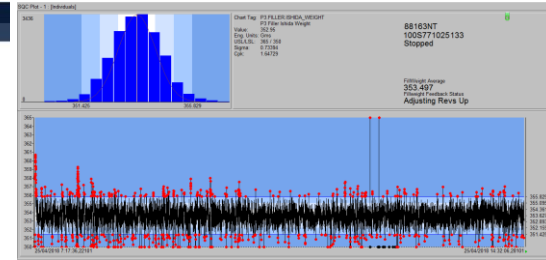
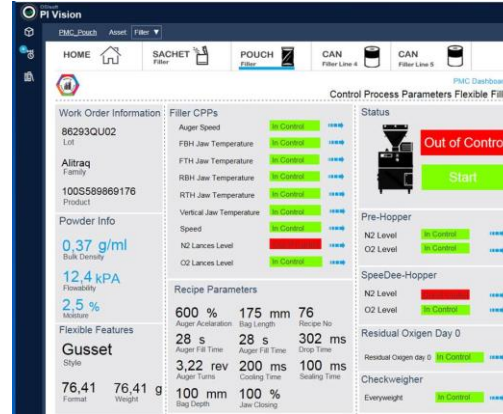
- **PI tools:**

- PI Datalink
- PI Vision.
- PI Process Book.

- **Analytics Tools:**

- Minitab.
- SEEQ

- **SQC - InfinityQS.**



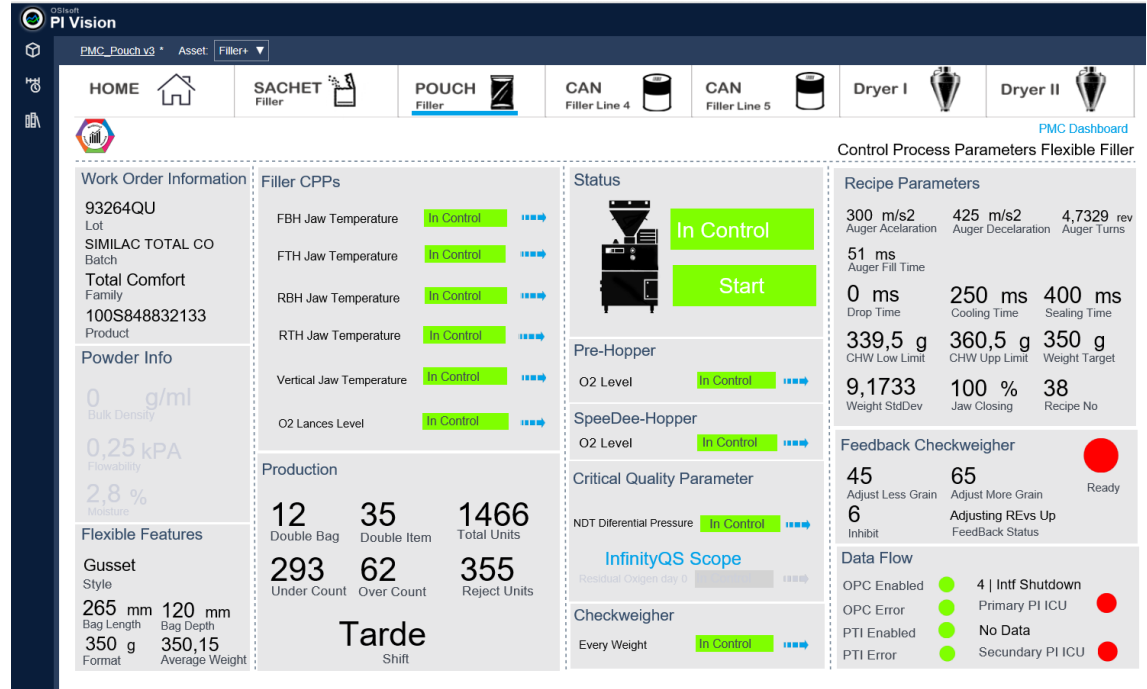
# Shop Floor Visualization

## Continuous Monitoring

- All CPPs are in control
- All Recipe Parameters are according to the Master Recipe
- Powder Info is not affecting to the filling process
- Overfilling is under warning limit.

## TIERs meetings

- Out of control events evaluation
- Root Cause Analysis support
- Escalation to Front Line Leaders and Management Team.





# Shop Floor Visualization - RCA

## Root Cause Analysis Support:

Current Value

Target

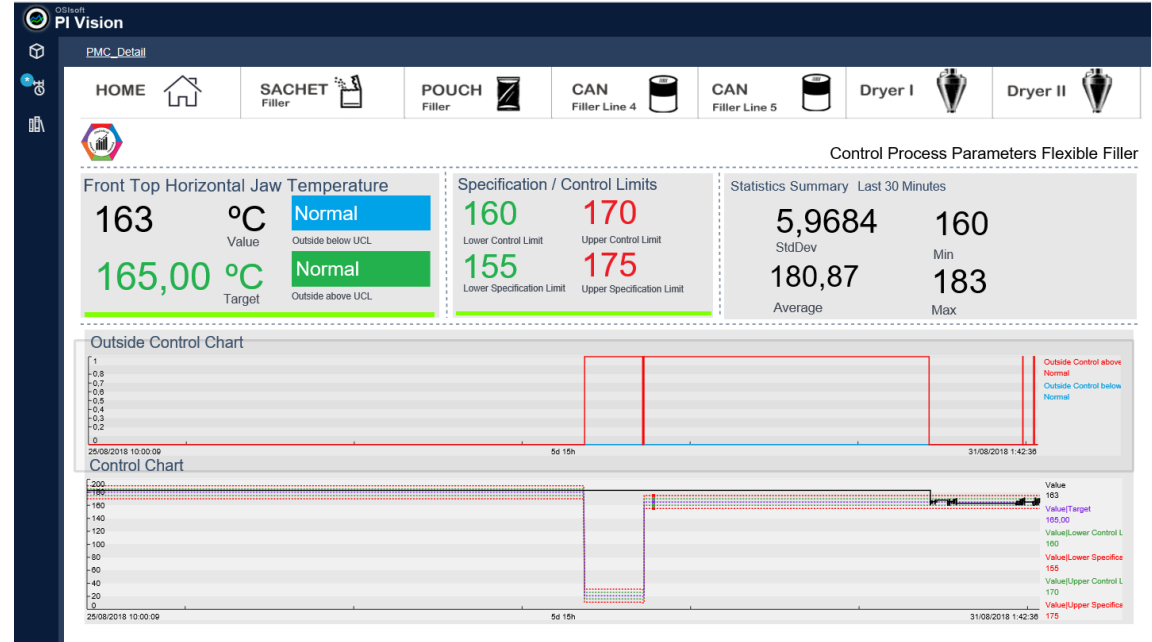
Specification Limits

Control Limits (Minitab study)

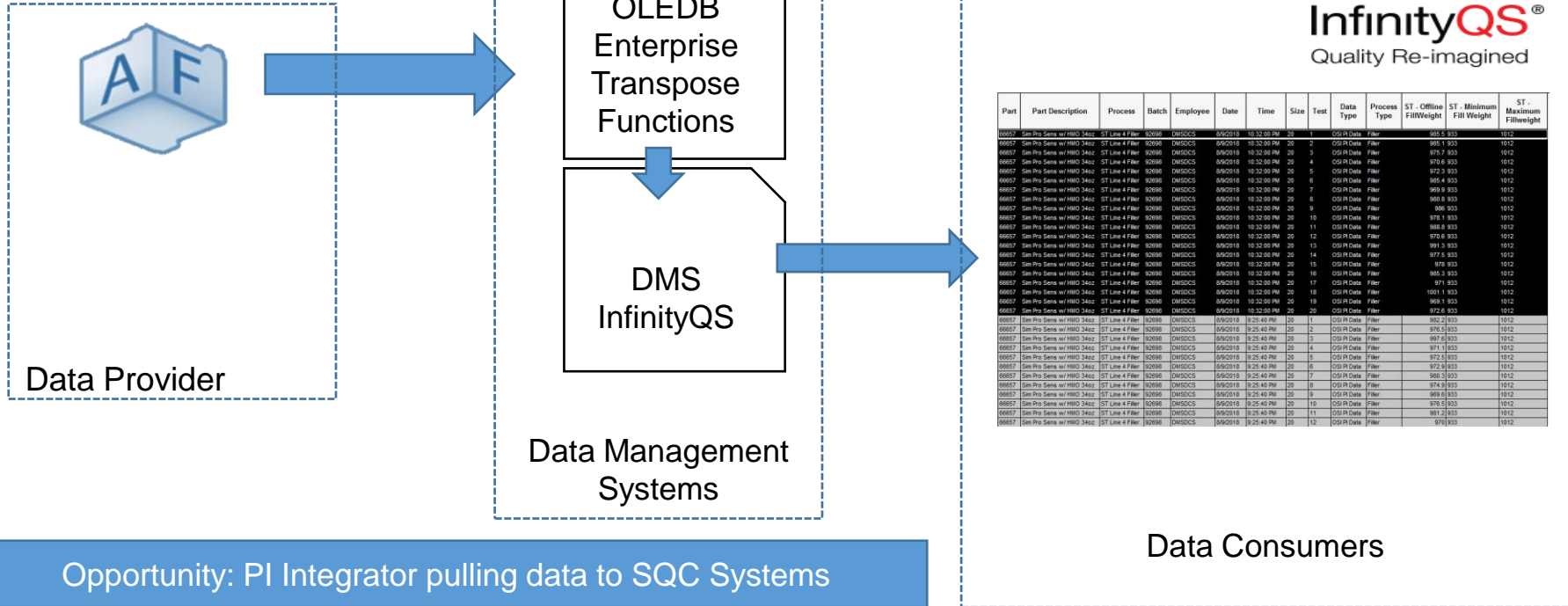
Last 30 minutes statistics summary

Control Chart

Outside Control Chart Events



# OLEDB pulling data to external SQC Applications



Opportunity: PI Integrator pulling data to SQC Systems

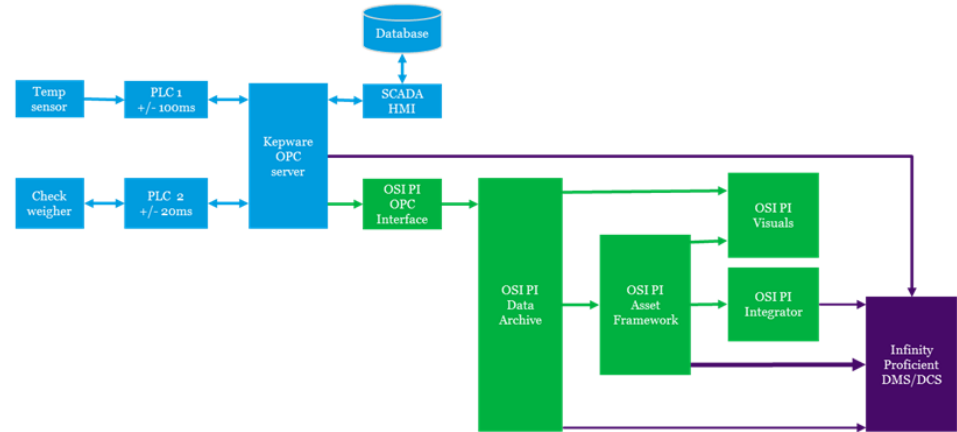
# What to validate and how

## 1. Equipment Level

- Filler
  - Every Weight Data collection
  - Feedback Dosing System
- Leak Tester Device
  - Software Update ( OPC ).
- Oxygen analyzer
  - Configuration Changes.

## 2. OPC Layer

- Kepware Nodes.
- Third Party OPC Servers
- Third Party Software allowing the data collection



# Data Flow – Data Integrity

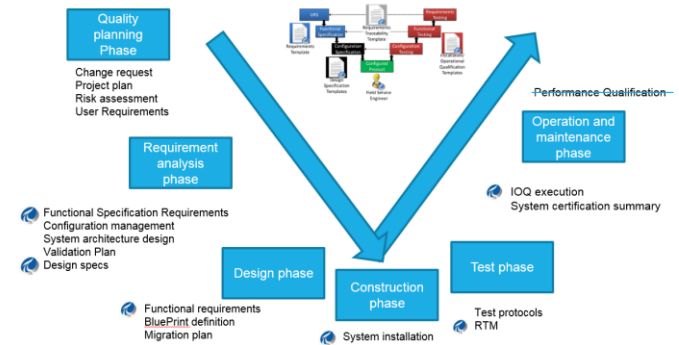
## What to validate and how

### 3. PI Infrastructure (validated environment).

- PI Interfaces (ICU)
- PI Vision in production environment.
- PI Integrator in production environment (Opportunity).

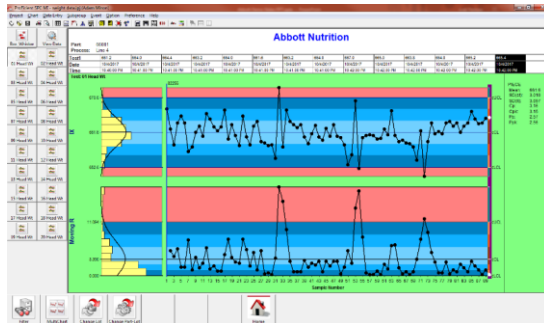
### 4. PI PMC Application

- PMC Data Collection GR Flexible Lines.
- Visualization of the newly created PI Points and screens on PI Vision.
- Verification of the PI AF/EF Templates including all Analysis (Expression, Event Frames and SQC).
- Verification of the creation of the necessary Elements.
- Verification of the capability of the system to provide information to external SQC applications (InfinityQS, Minitab).





# Power of data

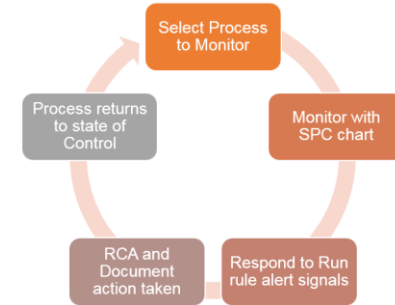
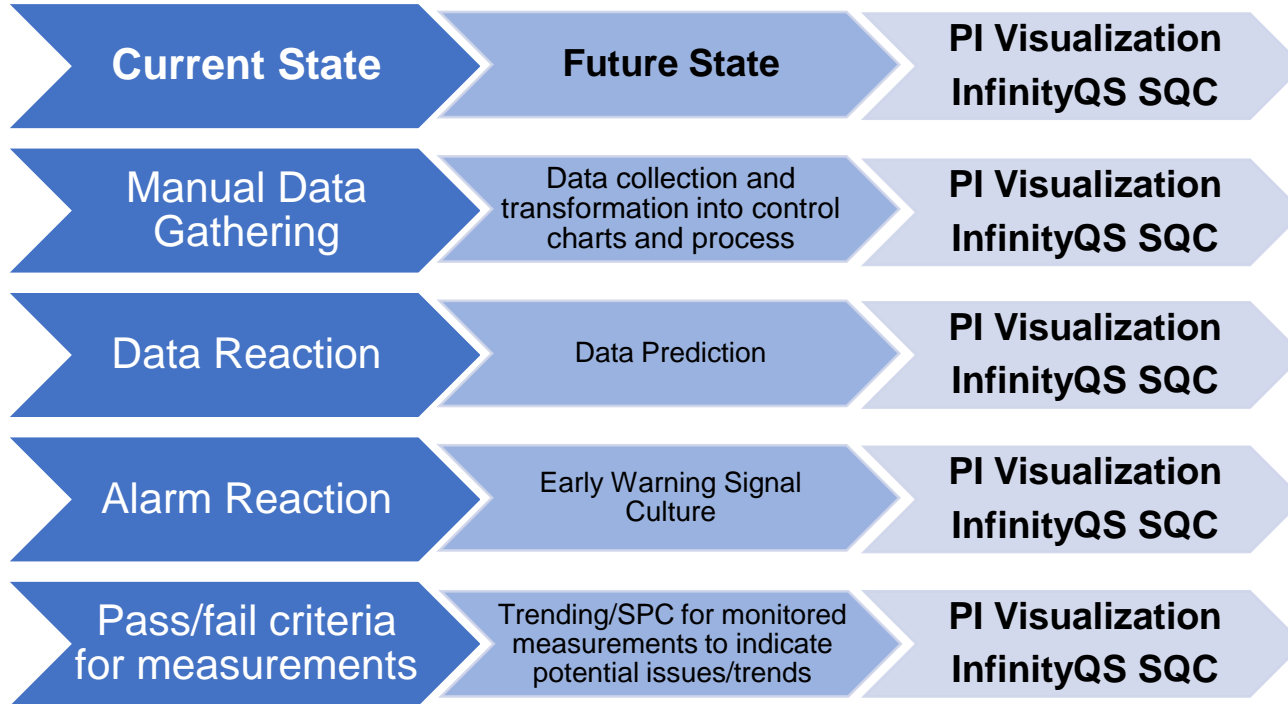


- 100% Electronic data collection.
- CPPs – CQAs identified
- Visualization ready.
- System Data providers Infrastructure validated.
- Variation reduction and control limits defined.
- Gold Standard Designs Replicated site by site.
- New SPC tool successfully adopted by the site

# Business Benefits

- PMC **improved understanding** and use of critical OSIPi tags and data to drive value
- Main benefit has been targeted application of PMC principles to generate **CIP savings**
- Data visualization has **helped operator** engagement and understanding of CPP's
- Implemented Systems and tools Allowed the plant to **proactively collect data and use.**
- Creates pathway for **replication** on other lines.
- Resource awareness started with a single person and has now **grew into a team.**

# Reaction Plan



# Standardization

- Global PI Architecture and software versions guideline.
- Common PI AF model based in templates.
- Common visualization using PI Vision.
- Site OPC layer providing context to the data.
- Validation strategy supported using OSIsoft templates.
- PI Integrator pulling data to external SQC Systems.





# Abbott Nutrition

Using SQC PI Analysis to reduce number of exceptions with a results in lower cost of quality



## CHALLENGE

Better understanding our flexible processes identification and monitoring of the main CPP's and CQA's helping to reduce risk of leak events.

- Focus on the Pouch Filling Area SPC thought DMAIC strategy.
- Quality Events, scrap and OEE as main drivers.

## SOLUTION

PI SQC Analysis and PI Vision showing the data to the operators and PI OLEDB Enterprise pulling data to the global SQC application.

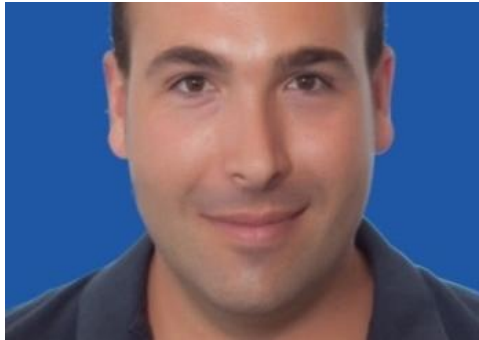
- Data is already present in PI Archive
- PI AF and Analysis providing a shop floor SQC realtime solution sampling 100 % of the data and standardization platform across the sites.
- PI as data provider to global SQC tools.

## RESULTS

Leverage PI tools to monitor our pouch filling processes with no quality events and good line efficiency.

- Monitor the process using control charts.
- Control Limits are now telling the story.
- Understanding and use of CPPs and CQAs.
- OEE Improvements (~2%)
- SCRAP Reduction in row and packaging material due better quality performance.
- Potential opportunity to screen the filler speed.
- No leaks events related with filling process.

# Using SQC PI Analysis to reduce number of exceptions with a results in lower cost of quality



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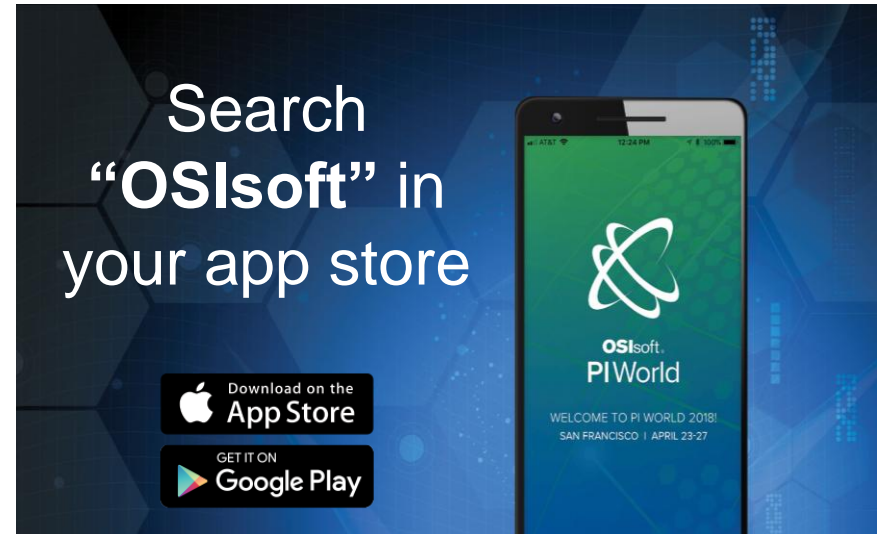
# Questions?

Please wait for  
the **microphone**



State your  
**name & company**

# Please rate this session in the mobile app!



謝謝 KEA LEBOHA  
 TAPADH LEIBH 고맙습니다  
 БАЯРЛАЛАА MISAOTRA ANAO  
 DZIĘKUJĘ CI NGIYABONGA TEŞEKKÜR EDERIM GRACIES OBRIGADO شكرا SALAMAT  
 KÖSZÖNÖM DANKIE TERIMA KASIH DANKON TANK TAPADH LEAT  
 СПАСИБО МУЛТUMESC  
 PAKMET CIZGE GO RAIBH MAITH AGAT OSIssoft. HVALA FAAFETAI  
 БЛАГОДАРЯ GRACIAS MAHADSANID HVALA ESKERRIK ASKO  
 TI БЛАГОДАРАМ HVALA ХВАЛА ВАМ  
 TAK DANKE MAHANSANID TEŞEKKÜR EDERIM  
 RAHMAT MERCI DANK JE EΥΧΑΡΙΣΤΩ GRATIAS TIBI GRAZIE  
 HATUR NUHUN AČIŮ SALAMAT MAHALO IĀ 'ŌE TAKK SKALDU HA DI OU MÈSI  
 GRAZZI ПAKKA PĒR ありがとうございます ǃAKUJEM  
 PAXMAT CAĜA SIPAS JI WERE TERIMA KASIH MATUR NUWUN  
 CẢM ƠN BẠN UA TSAUG RAU KOJ  
 WAZVIITA TI БЛАГОДАРАМ  
 СИПОС  
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THANK YOU