



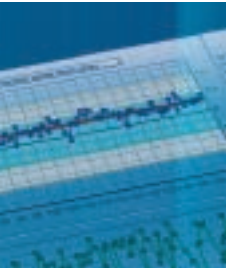
## Statistical Quality Control solutions

- Save money by reducing overfilling
- Fulfill legal and regulatory requirements
- Optimise process control
- Streamline internal quality procedures

# Excellence in Statistical Quality Control

METTLER TOLEDO

# Fulfill net content legislation and save money



Sampling of fill quantities (liquids, viscous, powders or solids) following the filling process allows either an operator or a machine to immediately and precisely know when a product is trending to an out of tolerance condition. Adjustments are made through operator intervention or closed loop control to the filler from a dynamic checkweigher. Legal fill quantities and net weight regulations are met and unnecessary material losses are avoided, production processes remain in compliance with internal and external standards like Net Contents Legislation, ISO or GMP – our systems provide the statistical data needed to document, control optimise profitability.

Our solutions for Statistical Quality Control combine ease of operation, quality data management and analysis functionality.

- From mobile compact solutions with embedded SQC intelligence to networked systems with an SQL database
- The systems are upgradeable and can be expanded in line and adapted to meet changing customer needs
- Simple and intuitive masks guide the user through the sample process, reducing costs associated with training as well as errors during sampling process

## Customer requirements



- Minimise overfilling and reduce cost associated with material usage – immediate corrective actions based on online data analysis (alarms, graphics)
- Compliance with legal requirements in net content control of packages – guaranteed availability of historical data for legal evidence and extensive Q-analysis
- Fulfill FDA and other regulations for audit trail and process control, such as 21CFR Part 11
- Simplify and streamline quality control processes
- Real time access to current quality related production indicators, including variable and attribute control charts, histograms and other standard SPC analysis tools
- Network access to quality results, ability to view line and product results at remote plants and locations



## Benefit calculation: Improve filling accuracy and maximise profit

Parameters	Value	Unit
Raw materials costs	1.-	EUR/kg
Packages produced	100'000	quantity per day
Nominal fill quantity	100	g
Production days	250	days per year
Production mean value	101	g
Overfill per package	1	g
Overfill per day	100	kg
Overfill per year	25'000	kg
<b>Overfill loss</b>	<b>25'000.-</b>	<b>EUR/year</b>



Picture courtesy Schering



# Networked solutions FreeWeigh.Net

Networked system with vast expansion potential – to connect to virtually any device for instant data collection, analysis and action.

- Powerful quality assurance system – completely covers all aspects of packaging and filling quality control
- Statistical quality data is evaluated and presented online on customer designed graphic screens and freely definable reports
- Balances, scales, checkweighers, metal detectors and other devices can be integrated
- Supports separate work stations for product definition, monitoring and recording of measurement results from samples or 100% control
- Devices are linked by Ethernet TCP/IP, data stored on MS SQL database
- The modular structure of FreeWeigh.Net allows scaleable solutions and customisation

# Stand alone solutions FreeWeigh.Net Compact

Compact single-user SQC system with the capabilities of a large control and statistics programme

- Easy-to-create informative reports and statistical evaluations
- Traceable process and batch documentation as required by GMP and legal authorities
- Intuitive operator guidance and automatic data evaluation
- Option for 21 CFR Part 11 compliance with electronic signatures and audit trail
- MS SQL database
- Can be extended to create a networked FreeWeigh.Net multi-user quality assurance system



MS SQL server



Remote weighing station



Checkweigher



Metal detection



Testplace module with weighing station, tablet tester and dimension measurement

## Global solutions and experience

Solutions	Compact		Stand alone	Networked
	SQC14	SQC16/AX	FreeWeigh.Net Compact	FreeWeigh.Net
Max. products stored	16/60	300/100	Unlimited	Unlimited
Tolerance check	■	■	■	■
Control charts	■	■	■	■
Histogram	■	■	■	■
Mean and Standard Deviation monitoring	■	■	■	■
Local report strip printer	■	■	■	■
Reports letter printer	■	■	■	■
Batch statistics	■	■	■	■
Batch tracking	■	■	■	■
Adjustment messages	■	■	■	■
Warning messages	■	L	■	■
Operator identification	■	■	■	■
Graphic display	■	L	■	■
Electronic activities history	■	■	■	■
21 CFR Part 11 audit trail	■	■	■	■
3rd party device connectivity	■	■	■	■
Attributes and test plans	■	■	■	■
Ethernet device connectivity	■	■	■	■
Real time process monitoring and alarms	■	■	■	■
Distributed data acquisition	■	■	■	■

(L=Limited)

## Compact solutions SQC16

A compact system for efficient net weight control and fill quantity control:

- Flexible and powerful for 300 articles
- Statistical analysis and graphical representations
- Totals, mean, range and standard deviation by product
- Long term and batch statistics
- Output to graphic display as well as to an A4, US letter size or strip printer
- Keyboard and barcode reader interface
- Can be connected to a PC for data input and archiving
- Optional internal battery
- Compact scales from 3kg up to 35kg
- Resolutions from 0.01g up to 10g
- IP65 terminal with platforms up to three tonnes



Batch Report: PENNE RIGATE 067533 20.10.2011 09:13

Operator:	M. Sponhard	Article:	Penne Rigate
Batch:	067533	Net:	20.00 g
Min:	18.00	Tare (G):	
Nominal:	300.00 g		

Tolerance System: (G) →

CT2-	0.00 %	20.00 g
CT1-	0.00 %	15.00 g
CT1+	0.00 %	15.00 g
CT2+	0.00 %	20.00 g

Batch Results 32 operations (1 = 1) = 40

From:	20.10.2011 09:00	To:	20.10.2011 09:14
Mean:	181.30 g	300.320 g	
Std. Dev.:	1.83 g	3.160 g	
Minimum:	99.61 g	261.00 g	
Maximum:	182.97 g	317.84 g	
Range:	8.36 g	56.84 g	

Class Tables:

CT2-	0.00 %	0
CT1-	0.00 %	0
CT1	1.60 %	1
CT1+	0.30 %	0
CT2+	18.10 %	11
CT3-	34.60 %	20
CT3	31.67 %	19
CT3+	13.00 %	8
CT4	15.00 %	9
CT4+	3.20 %	2
CT5	3.20 %	2
CT5+	0.00 %	0

Violations:

CT2-	0	0.00 %
CT1-	0	0.00 %
CT1+	0	0.00 %
CT2+	0	0.00 %

Batch Totals: 3167 g

SQC Solutions

## SQC-AX

High resolution SQC system for small products such as tablets or capsules.

- Large graphics display with touchscreen operation
- Up to 100 products
- Supports automatic tablet feeder (LV11) for loading small items on the balance automatically



## SQC14

Combines keypad, SQC software and printer into a single unit for maximum space utility.

- Database for up to 60 products
- Graphical representation of results on printout
- Up to two independent sets of statistics per product to satisfy requirements of domestic and export markets
- Trend analysis with alarms
- User login and authentication
- User definable tolerance systems

For balances and scales from micrograms to tonnes – XS precision and XS analytical scales, PB-S, AB-S, BBA422, BBK422, BBA425 or IND425



Batch Report: Penne Rigate No73

ID:	No73
Me:	0076002005730
Batch:	067533
Nominal:	500.00 g
Tare (G):	20.00 g

Statistics:

1	494.51	1	1	1
2	502.14	1	1	1
7	506.99	1	1	1
4	501.33	1	1	1
5	509.38	1	1	1
Σ	189.57 %	502.070 g		
σ	1.14 %	5.748 g		
Min	98.98 %	494.51 g		
Max	181.08 %	509.38 g		
R	2.97 %	14.87 g		

Tolerance System:

CT2-	0	0.00 %
CT1-	0	0.00 %
CT1+	0	0.00 %
CT2+	0	0.00 %

Printout:

Chart	X Chart
1	1
2	1
7	1
4	1
5	1
Σ	5
σ	1.14
Min	98.98
Max	181.08
R	2.97
Items	5

Sample 15

12	500.617 g
	6.757 g
	1.35 %

## The right quality solution for every task.

No matter where you work in the company – METTLER TOLEDO SQC solutions prepare the data the way you need – helping you to optimise your workflow.

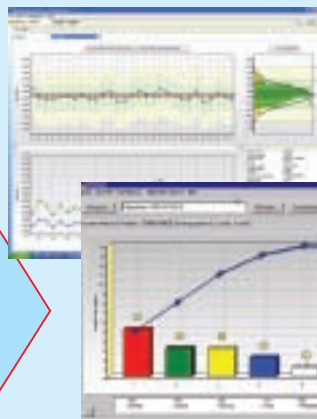
### Line operator

"I'm responsible for about 12 dairy products from 4 lines. In the past I had to check sample size, write down product ID and batch, record the net weigh result as well as the time and date. Now this is all done for me. I log in, scan in the batch and the product numbers, and the rest is up to the scale. Once I've completed the required weighments, I see a simple text message with the sample average and standard deviation. If the machine needs adjusting, the scale tells me how much. At the end of the batch, I automatically get a report of the results to pass on to my supervisor. Quick and easy."



### Production manager

"In my chocolate factory, I have invested \$ 180'000 in a FreeWeigh.Net system for seven packaging lines, scales, software, network and training. We got a fantastic pay-back of 3 months! Most importantly, I receive immediate feedback from the measuring equipment itself, as soon as we're not producing to spec. With the built-in machine adjustment algorithms I know that the operators aren't over-adjusting the machines. This means that they're free to be focused on other value-added tasks."



- Net content
- Expire date
- Batch/lot identification
- Package appearance
- Package insert included
- Tablet appearance (surface, embossement, color, etc.)
- Single and mean weight, thickness, diameter, hardness, friability, disintegration, dissolution



Picture courtesy Schering

### Plant manager

"Before we installed FreeWeigh.Net we "only" lost 5g on every bottle of lubricants filled. In total, however, that amounted to \$137'000 per year. FreeWeigh.Net also helped us increase our throughput by reducing giveaway per package which increased our yield per batch."



### Quality manager

"FreeWeigh.Net offers me a system that reduces the amount of time spent writing manual reports and to process them. Plus, best of all is that I do not have to enter the data into SAP anymore – FreeWeigh.Net does this for me automatically."



## Professional services



### Computer system validation for trouble free audits

More than just complying with federal GMP/GAMP regulations, computer system validation (CSV) defines, proves and ensures the reliability and consistency you require in process performance. By using the ready-made validation protocols from METTLER TOLEDO, you can save time and money in this labour-intensive process.

Our documentation of FreeWeigh.Net encompasses software development documents, such as specifications and test reports, describing the METTLER TOLEDO quality management system of software development as well as comprehensive protocols for installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ). The METTLER TOLEDO CSV Pacs – the professional computer system validation at your finger tips



#### Share our knowledge

Our information, knowledge and experiences are at your disposal in print or on-line

- FreeWeigh.Net
- FreeWeigh.Net compact
- SQC16
- SQC-AX
- SQC14
- Net weight in pharma production
- Validation



### Project management and coordination

Comprehensive feasibility studies ensure that all customers' expectations are met. Our experienced project engineers plan and organise installation, startup and training for immediate system availability and optimal use.

### Database and ERP integration

Appropriate file structure and database architecture (MS SQL, Oracle) provide the right data in the automation level of your choice.

### ServiceXXL Tailored Services

- Integral service concept
- Individually assembled service packages
- Priority service status
- Calibration certificate issued on site
- Minimum weight defined with MinWeigh

Sales and service:

[www.mt.com/sqc](http://www.mt.com/sqc)

**Mettler-Toledo GmbH**, Industrial  
Sonnenbergstrasse 72, CH-8603 Schwerzenbach, Switzerland

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#### Quality certification.

Development, production and auditing in accordance with ISO 9001. Environmental management system in accordance with ISO 14001.



#### Worldwide service.

Our dense service network, among the best in the world, ensures the maximum availability and lifespan of your product.



#### «Conformité Européenne».

This label is your guarantee that our products conform to the latest guidelines.