

# White Paper Investigating the Benefits and Challenges of Using OEE in Life Sciences

## Table of Contents

Introduction .....	3
What is OEE? .....	3
The Benefits of Measuring OEE .....	4
Real-time Batch Progression Monitoring .....	4
Assists Long Term Investment Decisions .....	4
Monitor and Minimise Changeover Time .....	4
Reveal Repeated Minor Issues.....	4
A Versatile Tool.....	4
Unleash Advanced Analytics .....	4
The Challenges of Measuring OEE in Life Sciences .....	5
Revalidation of Hardware .....	5
Validation of OEE Software .....	5
Integration with Existing IT .....	6
Supportability, Maintainability, Repeatability and Scalability .....	6
Maintaining Security and Integrity of Existing Systems .....	6
Variable Work Patterns.....	6
The ATS Intelligence Solution .....	6
Collecting Essential Data.....	6
Manual and Automatic Data Collection.....	7
Batch and Material Tracking.....	7
Generating Reports .....	7
Real-Time Data on Dashboards .....	8
Future Proofed for Additional Machines.....	8
All the Advantages of the ADOS Suite.....	8

**The Benefits and Challenges of Using OEE in Life Sciences**

A Production Line Example ..... 9

    Overview of Line..... 9

    Method of Data Collection ..... 9

    Local Network Configuration ..... 10

Conclusion ..... 10

## The Benefits and Challenges of Using OEE in Life Sciences

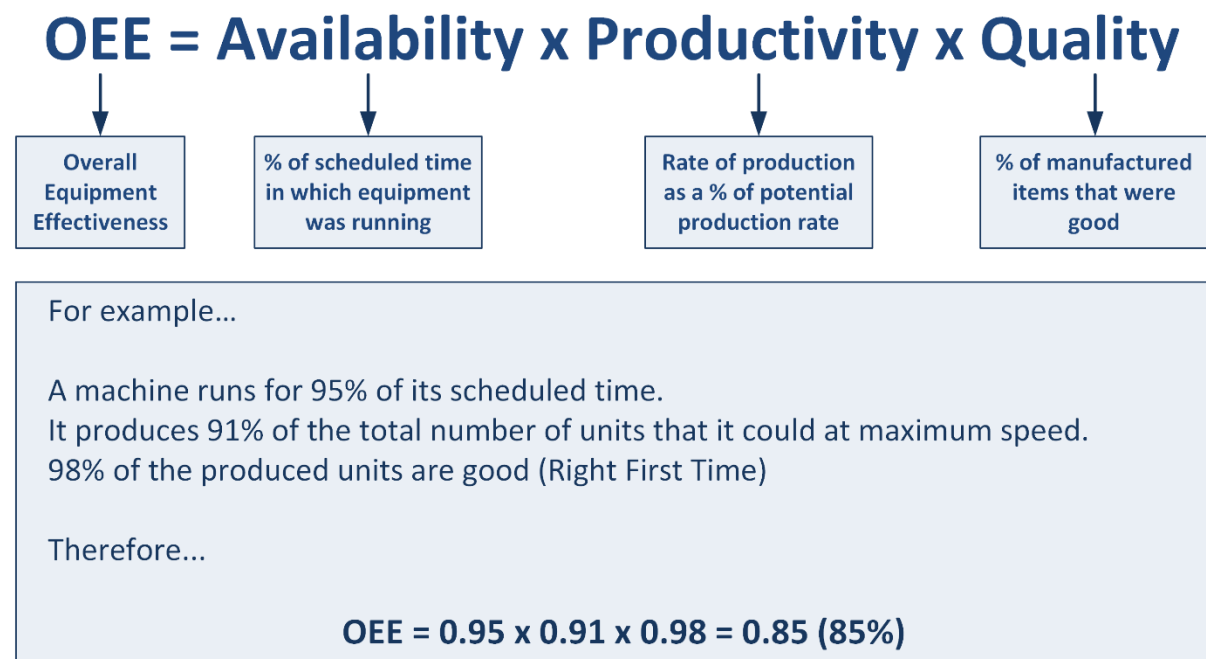
### Introduction

In this paper we'll look at the benefits of measuring OEE while also considering the specific challenges that face manufacturers wishing to implement an OEE solution within the Life Sciences industry. Finally, we'll present a potential solution that takes into account all of the requirements of the Life Sciences industry.

### What is OEE?

Overall Equipment Effectiveness (OEE) is a proven method for analysing how effectively manufacturing processes are operating. Developed in the 1960's it gives a generic set of results that can be used to highlight issues at any level, from an entire production plant to a single machine with the standardised results allowing comparison to be carried out between any kinds of processes.

The graphic below shows how the OEE is calculated.



Although OEE is now well established in most industries it still needs to be approached with careful planning so that the full potential ROI can be realised. The life sciences industry has particularly high requirements for product quality. This means that manufacturing equipment can be extremely expensive so when a new production line is put into action the Overall Equipment Effectiveness (OEE) needs to be pushed as high as possible to ensure a solid return on investment.

# The Benefits and Challenges of Using OEE in Life Sciences

## The Benefits of Measuring OEE

### Real-time Batch Progression Monitoring

Production managers are able to monitor batch progression and can estimate batch completion time. This is an essential tool for making real-time planning decisions such as whether overtime will be required or whether a delivery truck should be held back to wait for the completion of an order.

### Assists Long Term Investment Decisions

The OEE doesn't just show how the equipment is doing today - it also generates options when decisions are needed on future investment within the plant. When an increased output is required it may be possible to find areas where the productivity, availability or quality can be raised within existing equipment more cheaply than by buying in new equipment.

### Monitor and Minimise Changeover Time

Changeover times can have a serious impact on production rates. By monitoring the OEE of equipment within a plant these downtimes can be scrutinised and reviewed. If they are seen to be having too great an effect on profitability resources can be diverted to reduce the changeover time to a minimum.

### Reveal Repeated Minor Issues

OEE can highlight the smaller issues that may not be known about. It could be something as simple as the occasional realignment of a tool or a change in label. If it only takes a short amount of time then it's possible that it may be viewed as unimportant.

However, if these micro-downtimes are repeated frequently enough then they could affect the efficiency of the system. By monitoring the OEE in each process these seemingly minor issues can be highlighted and resolved.

### A Versatile Tool

The collection and calculation of OEE data can be carried out at any stage of the production line as it is entirely process independent. This gives you a powerful method that can be utilised in every area of the plant using a single tool to show the results.

### Unleash Advanced Analytics

In both the short and long-term OEE gives a management team access to a wealth of data that can be used beyond the bounds of the simple formula of OEE itself. When this data is combined with other data, such as which material is being used in the manufacturing process or what the temperature or pressure of the equipment was at the time of the readings, then a whole array of new data extrapolations become possible.

## The Benefits and Challenges of Using OEE in Life Sciences

The monitoring of OEE can also help a company attain its Lean and Six Sigma goals. For example, bottle necks can be easily identified so that line balancing can be improved and changeover times can be analysed and then reduced using methods such as Single-Minute Exchange of Die (SMED).

At every step the data gathered within the OEE structure is essential to the continuous process improvement within the plant.

### The Challenges of Measuring OEE in Life Sciences

#### Revalidation of Hardware

When setting up automated data acquisition, revalidation can often be required to ensure that a machine hasn't been affected in a way that would have any impact on the quality of the final product.

However, an OEE system can be implemented in a way that avoids the requirement of costly and time-consuming revalidation. For example, by incorporating an additional independent PLC, communication with the machine can be carried out without impacting on existing PLCs.

#### Validation of OEE Software

Generally, OEE software solutions are not subject to rigorous validation protocols, as OEE software solutions do not have any impact on materials or equipment sets. Although a risk assessment will be required, as it's a production performance measurement tool, it will not impact on the quality of product being produced in the same way that something like a MES would. The table below shows how OEE software is generally registered on a risk assessment.

Level of Concern	Software/Computer Systems Type				
	1	2	3	4	5
Minor			OEE Software		
Moderate					
Major					

- Type 1: Operating Systems
- Type 2: Firmware
- Type 3: Off the Shelf (OTS) Software/computer system
- Type 4: Configurable Off the Shelf (COTS) Software/computer system
- Type 5: Custom (Bespoke) Software/computer system

# The Benefits and Challenges of Using OEE in Life Sciences

## Integration with Existing IT

The IT systems of all large enterprises have been developed over time to cope with the unique challenges of each plant. Any OEE solution needs to be able to fit in with the existing IT system and integrate its reporting capabilities with those already in use.

## Supportability, Maintainability, Repeatability and Scalability

Getting an OEE solution isn't simply a case of buying a piece of software, installing it and watching the data roll in. The OEE solution needs to be able to expand as the plant expands, with more data being received from more machines. This means that installation and setup procedures need to be highly repeatable. Support and maintenance need to be kept to a minimum and with OEE this can normally be achieved by ensuring the implemented solution is as simple and reliable as possible.

## Maintaining Security and Integrity of Existing Systems

The security and integrity of the systems in place need to be maintained. Additional systems can add networking issues and may also face complications due to existing security protocols. This can be avoided by placing the data collection system alongside the existing system.

## Variable Work Patterns

Life Science manufacturing often involves frequent product changeover and shift pattern changes as well as plants running 24 hours a day, seven days a week. Any OEE solution to be implemented needs to be able to stand up to this consistent kind of pressure.

## The ATS Intelligence Solution

ATS Intelligence offers a simple but flexible OEE solution. It focuses on the key goals of collecting the essential data and then providing the results to the relevant people in a relevant format.

### Collecting Essential Data

ATS Intelligence will collect and analyse the following data:

- The amount of product being manufactured.
- The machine or process manufacturing the product.
- The equipment's optimum rate of production.
- The reasons for downtime for a piece of equipment.
- Variable data from the equipment.

The only data that is collected is the data required to calculate the OEE and optional, time-stamped variable data from the equipment. These variable values, such as temperature and pressure during manufacturing can give clues as to where issues may lie if the OEE starts to drop.

# The Benefits and Challenges of Using OEE in Life Sciences

## Manual and Automatic Data Collection

ATS Intelligence allows you to choose whether you are going to collect data manually or automatically or, as is frequently required, a combination of the two.

Data can be collected automatically, directly from the production line, via OPC and XML files. Alternatively you can gather data manually at one station from several machines simultaneously. Storing the information directly in a central database, this paperless method reduces the chances of lost or misinterpreted data.

ATS Intelligence allows you to select which elements you wish to collect manually and which automatically with all calculations carried out between the two so that your data is reliable and complete no matter what combination you use.

To give greater visibility of the data being collected ATS Intelligence comes with a module that allows you to view the data signals being received via OPC and XML in real-time.

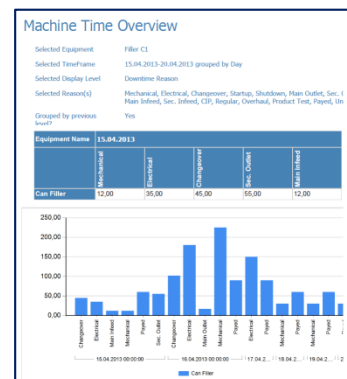
## Batch and Material Tracking

ATS Intelligence allows you to contextualise batch information by using real-time information gathered from the production line. If batch numbers are entered when adding production runs then it becomes possible to track its progress through the complete production process. Equally this will provide you with data regarding the time at which batches were started and how much material has been produced for that batch.

## Generating Reports

Using *ATS Advanced Reporting Services* all the data can be explored from anywhere in the world. With secure access to the report website no software is required on the machine on which the reports are viewed.

There are several ready-made reports that will break down the data into meaningful information and if there isn't a report that suits your requirements you can design and create one in-house utilising any of the available data you wish.

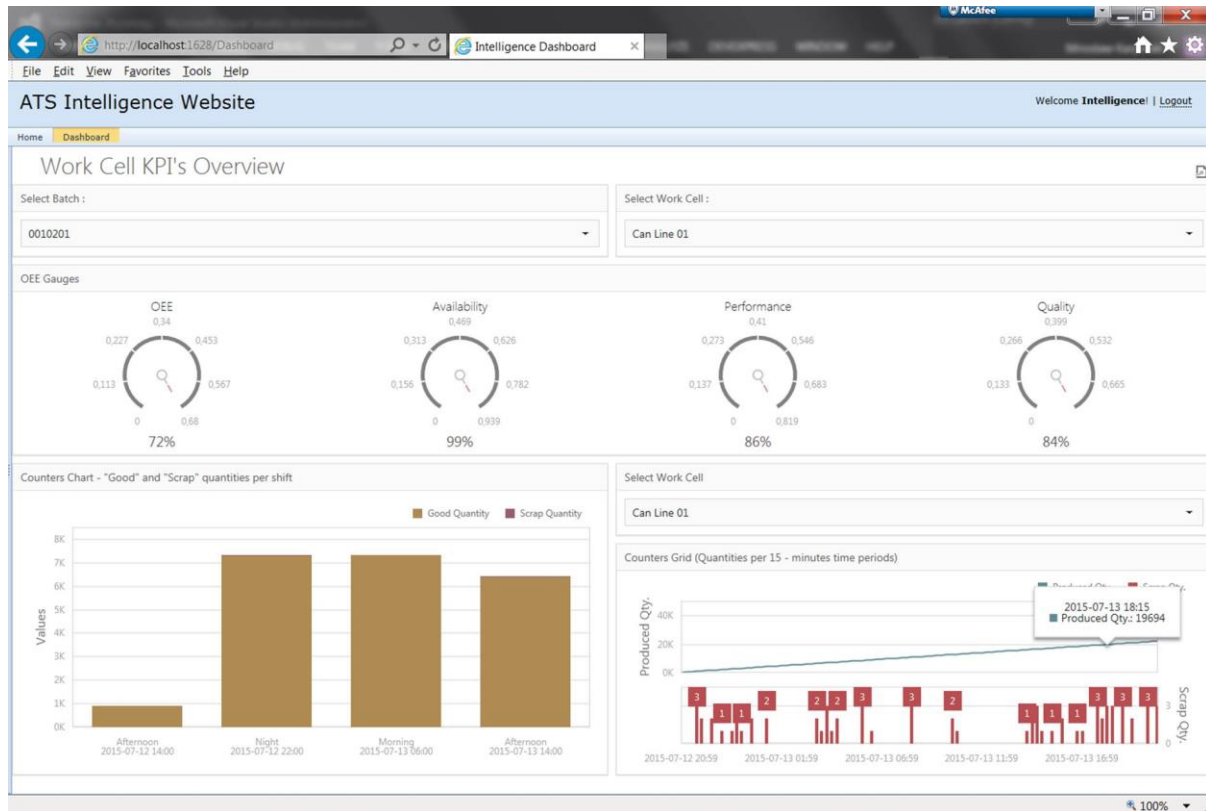




## The Benefits and Challenges of Using OEE in Life Sciences

### Real-Time Data on Dashboards

It's also possible to create dashboards so that real-time data can be viewed either remotely in an office or on an Andon screen on the production line. These fully customisable dashboards can show data for OEE, downtime and counters. Realtime feedback means that issues can be dealt with as soon as they occur, reducing downtime and costs.



### Future Proofed for Additional Machines

When modifications are carried out on the production line or other lines are included in the solution, ATS Intelligence allows you to add further machines to your existing implementation without re-configuring the existing setup. This allows you to easily scale-up your OEE operation without excess costs or re-training.

### All the Advantages of the ADOS Suite

ATS Intelligence is part of the ADOS (Attribute, Dimensional, Operational and Shared) software suite. ATS ADOS gives you world-class data collection, reporting and analysis while its cross-application integration provides endless avenues along which to develop and expand your manufacturing potential.

The ADOS suite was awarded Frost & Sullivan's 2014 Global Plant Data Management and Quality Optimization Solutions for Discrete Industries New Product Innovation Award.





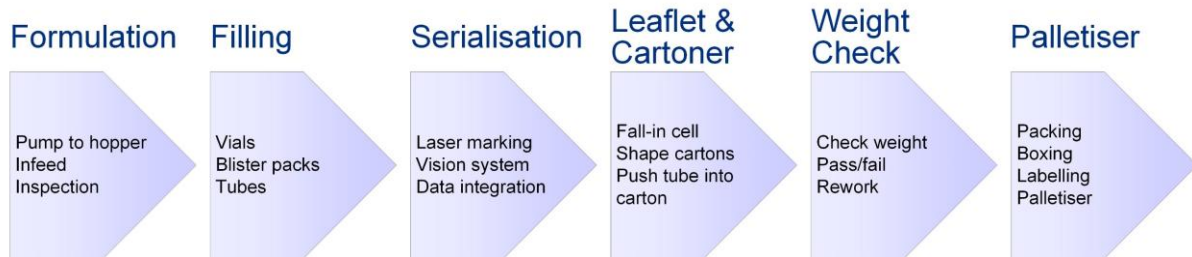
## The Benefits and Challenges of Using OEE in Life Sciences

### A Production Line Example

To see how an OEE solution could work in practice we'll use the following fill/finish production line.

#### Overview of Line

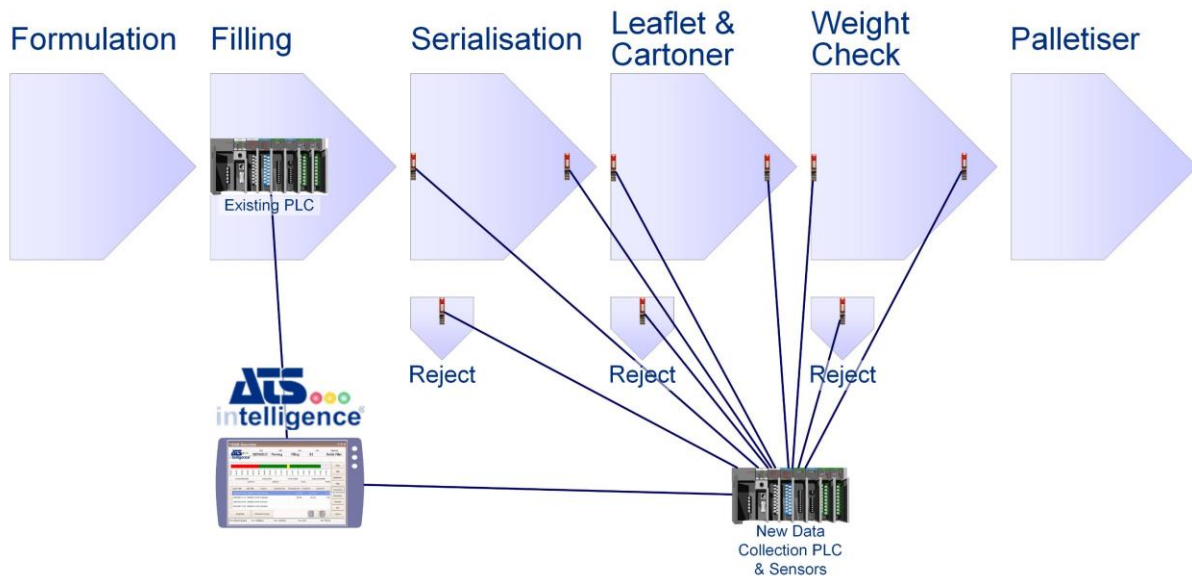
The production line contains six cells as shown below. The processes carried out in each cell are also shown.



#### Method of Data Collection

Some data is going to be collected manually and some automatically. The graphic below shows how automatic data collection is carried out.

All production data for the *Filling* cell is gathered directly from an existing PLC as it was possible to do so without impacting on the quality of the final product. However, most data is being collected via a number of sensors that have been installed separately from the existing system. The sensors, located in three different cells, all send data to a single PLC which then passes it on to ATS Intelligence.

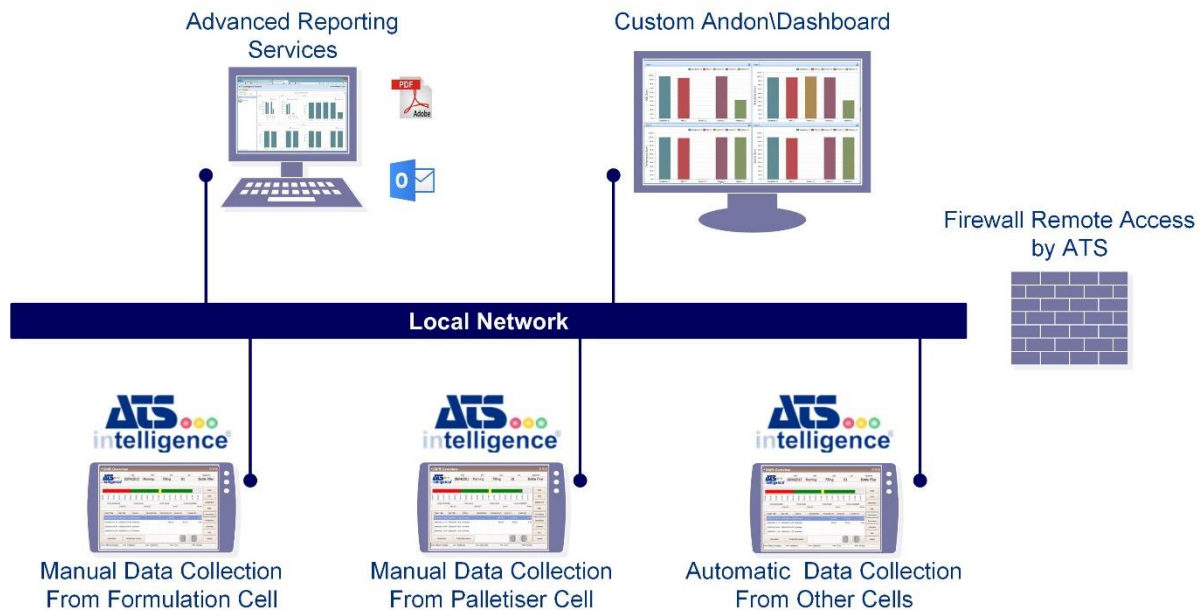


## The Benefits and Challenges of Using OEE in Life Sciences

### Local Network Configuration

As can be seen below, both manually and automatically collected data can be relayed through a local area network and made available in a number of different ways.

Andon screen can display OEE information to the shop floor in real-time using customisable dashboards. Alternatively the data can be viewed from anywhere with a secure connection to the network using ATS Advanced Reporting Services.



### Conclusion

As customers continue to expect ever higher quality and margins are pushed ever tighter the need to get the most from your production processes continues to increase.

The measuring of Overall Equipment Effectiveness (OEE) presents a way to monitor and react to conditions on the production line. By using additional sensors and PLCs this is also non-invasive meaning that the costs and requirements for implementation are greatly reduce.

ATS Intelligence is put forward as a complete solution for collecting and analysing OEE data in the life sciences industry.

As well as allowing both manual and automatic data collection ATS Intelligence also allows you to monitor batch and material progression throughout the plant. It also has the flexibility to grow as the size and complexity of your OEE requirements grow.

Data can be presented on the shop-floor using Andon screens or anywhere with a secure network connection using the web application, ATS Advanced Reporting Services.