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1. PURPOSE AND OBJECTIVES

The purpose of this document is to define how to calculate Manufacturing Lines Capacity and OEE (Overall Equipment Effectiveness) on the basis of their underlying terms. Manufacturing lines generally include filling, tabletting or packaging lines in Pharma manufacturing as well as trains of either bioreactors or chemical reactors and their associated downstream processes steps in Biologics, Vaccines and Small molecules drug substances manufacturing. The best way to get reliable OEE figures is to collect real time data along manufacturing lines. This document provides also advice for this purpose.

2. SCOPE AND APPLICABILITY

This standard applies to all manufacturing sites across Sanofi IA platforms.

It has to be observed by the Site's leadership team members, IA platforms Management and to be communicated to all users.

- Activity (i.e. domain) to which the document applies

☐ Clinical ☐ Country ☐ Distribution ☐ Information Systems ☐ Laboratory (GLP)	☒ Manufacturing ☐ Medical ☐ Pharmacovigilance ☐ Regulatory Affairs ☐ Research & Development (GRP)

- Product ranges to which the document applies

☒ Active Pharmaceutical Ingredient ☐ Combination Products ☐ Cosmetics ☐ Investigational Medicinal Products	☒ Medicinal Product ☒ Medical Devices ☒ Nutraceuticals ☒ Vaccines

3. REQUIREMENTS

3.1 DEFINITIONS AND ASSOCIATED REQUIREMENTS

3.1.1 ACRONYMS

AR: Availability Rate
CUF: Capacity Utilization Factor
ICT: Idle Capacity Time
LCT: Line Closing Time
LOQR: Line Output Quality Rate
LOR: Line Occupation Rate
MLC: Manufacturing Line Capacity
NOT: Net Opening Time
NPLO: Net Production at Line Output
OEE: Overall Equipment Effectiveness
eOEE: electronic OEE
OT: Operating Time
PCOT: Production Corresponding to Operating Time
PR: Performance Rate
PLSS: Performance Losses due to Short Stops
SST: Short Stops time
PLSY: Performance Losses due to Slowing down or Yield
PUST: Planned and Unplanned SToppages
QPR: Qualified Production Rate
QRJ: Quality Rejects
SDT: Scheduled Down Time
SA: Speed Adherence
SNOT: Standard Net Opening Time
TD: Technical Downtime
TPR: Total Production (NPLO + QRJ)
TPT: Total Potential Time

3.1.2 TERMS AND FORMULAS

3.1.2.1 OVERALL EQUIPMENT EFFECTIVENESS [OEE]

The OEE [%] is a standard indicator measuring equipment productivity for a given manufacturing line. It identifies the percentage of equipment's' time that is truly productive during the Net Opening Time and the corresponding Net Production at Line Output. The OEE is the product of three factors, a) the Availability Rate, b) the Performance Rate and c) the Line Output Quality Rate, which are described below.

$$OEE[\%] = \frac{1}{10\,000} * AR[\%] * PR[\%] * LOQR[\%]$$

An OEE of 100% means that only a fully “expected production” was manufactured, at the “qualified production rate”, with no stoppage, yield loss or slowing down, and no quality rejection. In this case, each of its three factors, i.e. the Availability Rate, Performance Rate and Quality Rate are equal to 100%.

The OEE must be understood as measuring it over an entire production line, and not at a specific equipment level. A production line is characterized upstream by the feed of raw materials and parts at the line input and is characterized downstream by the semi-finished or finished product/SKU at the line output. In other words, an OEE encapsulates several production steps which are continuous (masked-time production process is treated in chapter 3.3.2), in which each step influences the next one's output, with no way to make up for a lost production through intermediate buffers. The production steps of a line generally have the same qualified production rate or speed.

3.1.2.2 Total Potential Time [TPT]

Total Potential Time TPT is defined as the yearly calendar time in hours (or days or minutes).

TPT [DAYS] = 365 or 366 days. By convention TPT is always considered on a 365 days basis.

3.1.2.3 Line Closing Time [LCT]

Line Closing Time LCT [DAYS] is the sum of time when the line is Scheduled Down for:

- Bank Holidays Time BHT: The sum of days during which the manufacturing line is closed, say week-ends and public holidays.
- Big Preventive Maintenance Time BPMT: The long annual plant shutdown, whilst periodic planned maintenance times (monthly, weekly, daily) are not part of BPMT.
- Personnel Holidays Time PHT during which the manufacturing line personnel takes its statutory holidays, if not already computed as part of the BPMT, assuming the personnel is not replaced to run the line.
- New Product Development Time NPDT: The time during which the manufacturing line is reserved for (new) product development activities, line modification, testing, validation.
- External Factors Down Time EFDT: Unexpected line shutdowns which are not under the control of the line Management (ex. General power outage from the grid or lack of intermediate product from upstream manufacturing line).

$$LCT\ [DAYS] = BHT + BPMT + PHT + NPDT + EFDT$$

Note: In 24x7 operations, BHT, BPMT and PHT may equal to zero. As well, Preventive Maintenance may be carried out in masked time.

For the budget phase the categorizations here above must be based on assumptions or targets, whereas they must be measured for the actual OEE.

3.1.2.4 STANDARD NET OPENING TIME [SNOT]

The Standard Net Opening Time SNOT of a line is determined in function of the site manufacturing organisation and is used for the Manufacturing Line Capacity calculation.

$$SNOT\ [T] = TPT - LCT$$

More precisely the formula integrating a site's shifts organization is:

$$SNOT\ [HOURS] = (TPT - LCT) * Nb\ shift\ per\ day * Nb\ hours\ per\ shift$$

Site work organisation	5 days & 2 eight hours shifts	5 days & 3 eight hours shifts	24x7 operations
Line Closing Time LCT= BHT+BPMT+NPDT+PHT+EFDT	LCT= 112+20+5+11 = 148 days	LCT= 112+20+5+11 = 148 days	LCT=BMPT=14 days
Standard Net Opening Time (SNOT)	SNOT=(TPT-LCT) * shifts * hours per shifts = (365 – 148) * 2 * 8 = 3472h	SNOT=(TPT-LCT) * shifts * hours per shifts = (365 – 148) * 3 * 8 = 5208h	SNOT=(TPT-LCT) * shifts * hours per shifts = (365 – 14) * 3 * 8 = 8424h
Assumptions and comments	112 bank holidays, 4 weeks annual shutdown, one week validation, 30 personnel holidays with 19 Holidays taken during BPMT in average	112 bank holidays, 4 weeks annual shutdown, one week validation, 30 personnel holidays with 19 Holidays taken during BPMT in average	2 weeks annual shutdown, no NPDT and production sold out. Personnel staffed to ensure 24x7 operations

Table 1 : Examples of SNOT determination

Note 1: SNOT taken into consideration in Strat Plan is 5200 hours for Pharma sites

Note 2: SNOT taken into consideration in Strat Plan is 8760 hours for Chemistry and Biologics sites

3.1.2.5 NET OPENING TIME [NOT]

The Net Opening Time NOT is the time during which the manufacturing line is scheduled (Budget) or actually used (Actual production) in order to meet the requested production volumes.

For the budget:

$$NOT\ [HOURS] = OT\ [HOURS] + PUST\ [HOURS]$$

The terms used for NOT calculation for the budget phase are respectively defined in chapters 3.1.2.9 and 3.1.2.10. The actual NOT must be measured.

3.1.2.6 IDLE CAPACITY TIME [ICT]

The Idle Capacity Time ICT is the time scheduled down when the line is not needed to produce the requested volumes, i.e. when a line is not used at full-year capacity.

$$ICT\ [HOURS] = 24 * (TPT - LCT) - NOT$$

ICT results from the determination of the Net Opening Time [NOT], which is calculated in function of the yearly volumes needed.

3.1.2.7 Scheduled Down Time [SDT]

The Total Scheduled Down Time SDT is composed of the Line Closing Time LCT and the Idle Capacity Time ICT.

$$SDT\ [HOURS] = (24 * LCT) + ICT$$

3.1.2.8 Line Occupation Rate [LOR]

The Line Occupation Rate LOR is the ratio Net Opening Time / Total Potential Time. It characterizes how much time is available with the required personnel staff for production activities in comparison to the considered calendar time.

$$LOR\ [\%] = 100 * \frac{NOT}{TPT}$$

3.1.2.9 Planned and Unplanned Stoppages [PUST]

The Planned and Unplanned Stoppages Time PUST [HOURS] is the sum of:

- Change-Overs Time COT is the sum of all the times required until the next batch commences, including Cleaning In Process / Sterilization In Process as well as line reloading stoppages during production.
- Organisation Time ORT is the cumulated time lost due to non-readiness of the paperwork, raw material, parts missing, non-authorization to commence or continue production, breaks, meals, training and meeting time as long as these cause a production stoppage.
- Autonomous Maintenance Time AMT is the cumulated time of autonomous cleaning, tests, maintenance and adjustment activities that are carried out by manufacturing operators and cause a production stoppage.
- Preventive Maintenance Time PMT is the cumulated manufacturing line's maintenance times that are carried out by Maintenance Technicians and cause production stoppages, irrespective whether they relate to preventive and predictive maintenance and equipment calibration. PMT does not include AMT and Big Preventive Maintenance Time (Annual shutdown).
- Breakdowns Time BT is the cumulated times for stoppages due to either equipment and process control software failures or any time for corrective maintenance.
- Other and Unknown Stoppages Time OUST is the cumulated time of all other causes not listed above (ex: Stoppage for unknown or unrecorded reason. Stoppages recording must be reliable enough to keep OUST lower than 10% of the PUST).

$$PUST[HOURS] = COT + ORT + AMT + PMT + BT + OUST$$

Each of these categories has to be measured for the actual PUST. For the budget phase these categories are estimated as targets according to the Operating Time OT calculated (defined in the chapter 3.1.2.10 hereinafter).

Note: these main categories are common to all types of manufacturing processes, whilst sub-categories have to be defined at IA Platforms level, depending on specific manufacturing processes.

3.1.2.10 Operating Time [OT]

The actual Operating Time OT [HOURS] is the difference between the Net Opening Time NOT and the Planned and Unplanned Stoppages Time PUST.

$$OT[HOURS] = NOT - PUST$$

For the budget phase, the forecasted OT depends on the Net Production expected at Line Output NPLO, the Qualified Production Rate, the assumptions on Quality rejections and the Performance losses quantities.

$$OT[HOURS] = \frac{TPLO + QRJ + NPLO}{QPR}$$

The terms used for OT on Budget phase are respectively defined from chapter 3.1.2.12 to 3.1.2.16 hereinafter.

3.1.2.11 Availability Rate [AR]

The Availability Rate AR [%] is the first of the three factors entering in the OEE formula. The Availability Rate is the ratio Operating Time / Net Opening Time.

$$AR[\%] = 100 * \frac{OT}{NOT}$$

3.1.2.12 Qualified Production Rate [QPR]

The Qualified Production Rate QPR [SKU/T], also called qualified speed for a packing machine, is the instantaneous manufacturing line production rate of the line, for a given product/SKU, under stable conditions. QPR obviously excludes stops, as it reflects a continuous production state.

As a consequence, QPR may vary across different groups of SKUs for certain type of processes. Besides, QPR must be measured under similar conditions as equipment commissioning tests, in particular during sufficient time period of continuous production (no stop, slowdown, yield losses), to ensure it reflects a stabilized and maximum qualified production rate.

For filling and packing lines QPR is also called qualified speed and is often expressed in Units/SKUs per minute.

For API bulk production in chemistry, biologics activities, vaccines bulk production, QPR is usually expressed as Best Demonstrated Rate to produce a product batch in the corresponding time. In this case the QPR is expressed in product/SKU weight per time unit (Kg/hour or gr/hour).

The time between two product/SKU batches is excluded as this time is considered as Change-overs time COT.

3.1.2.13 PRODUCTION CORRESPONDING TO OPERATING TIME [PCOT]

The Production Corresponding to the Operating Time PCOT [T] is calculated by multiplying the Operating Time and the Qualified Production Rate. PCOT is the total production that could be reached during that Operating Time (Budget and Actual), assuming no product loss, nor product quality reject.

$$PCOT[SKU/TP] = OT[T/TP] * QPR[SKU/T]$$

Where the considered Time Period TP is the shift, day, week, month, year - usually the year - and T is the time needed for this SKU.

3.1.2.14 PERFORMANCE LOSSES

During the Operating Time, there are two types of performance losses that may occur:

- The Performance Loss due to Short Stoppages [PLSS]
- The Performance Loss due to Slowing down or Yield [PLSY]:
  - i.e. integrating the manufacturing line slowdowns during the period considered, usually resulting from a temporary reduction of the Qualified Production Rate (ex: speed reduction on a packaging line)
  - or the process or biological yield which is lower than 100% (ex: chemical reactor not producing at QPR)

3.1.2.14.1 PERFORMANCE LOSSES DUE TO SHORT STOPPAGES [PLSS]

A short stoppage is defined as a temporary stoppage which is not due to an equipment breakdown or a process failure, but typically due to a product clogging, sensor activation and lack of raw materials or components which requires an intervention of a manufacturing operator to resume the production. The duration of a short stoppage must be meant as a question of minutes for tableting, filling and packaging lines and somewhat longer for chemical and biologics processes. If production cannot be resumed by a manufacturing operator in that timeframe, the stoppage has to be classified under “Breakdown Time”.

As short stoppages are difficult to be reliably recorded by operators during production, they must be measured with online monitoring devices and the Performance Loss due to Short Stoppages PLSS may be calculated as the product of the actual Short Stoppages Time by the Qualified Production Rate.

$$PLSS\left[\frac{SKU}{TP}\right] = SST[\frac{T}{TP}] * QPR[\frac{SKU}{T}]$$

If the short stoppages cannot be measured or recorded manually, they must be estimated or considered as not relevant.

For the Budget phase PLSS has to be a target

3.1.2.14.2 Performance Losses due to Slowing down or Yield [PLSY]

The Performance Loss due to Slowing down or Yield PLSY is the integrated performance loss over the period considered and resulting from a process that is not operating at the Qualified Production Rate. PLSY is difficult to count or calculate, because it is an integrated performance loss over a period and only complex algorithms could calculate it, and as well a count is in most of processes not possible, especially in continuous or batch processes. Actual PLSY is therefore calculated by difference between the Production Corresponding to the Operating Time PCOT, the Performance Loss due to Short Stoppages PLSS, the Quality Rejects QRJ and the Net Production at Line Output NPLO.

$$PLSY\left[\frac{SKU}{TP}\right] = PCOT - PLSS - QRJ - NPLO$$

For the budget phase PLSY has to be defined as a target.

Note 1: Because the Change-Over Time finishes when the next batch commences, if any time is needed until the line reaches its QPR, the related production losses will be reflected into the PLSY. In other words, such a “Ramp-up” must not be part of the Change Over Time COT, as it is not a stoppage time.

Note 2: The Total Performance Losses [TPLO] is the addition of the two types of performance losses.

$$TPLO\left[\frac{SKU}{TP}\right] = PLSS + PLSY$$

3.1.2.15 Quality Rejects [QRJ]

Quality Rejects QRJ [SKU] is the actual quantity of products immediately rejected all along the production line, irrespective whether they are scrapped or reworked.

For the budget phase QRJ has to be defined as a target.

Note 1: As the Quality Department may reject products (SKUs or batch) well after these went out of the line, sometimes several weeks later, it would be retroactively complicated to recalculate the overall QRJ. This is why QRJ only considers the parts rejected immediately at the line during production. However, the Batches Released Rate BRR has to be considered for the NPLO calculation, as explained in the related chapter herein after.

Note 2: In some cases, the master data of the product are needed to convert items rejected in order to be consistent with the unit used for NPLO. For instance in packaging lines, two blisters rejected could mean only one box equivalent in QRJ, as well as one shipper rejected and reworked on the line could mean eighty boxes in QRJ.

3.1.2.16 Net Production at Line Output [NPLO]

The Net Production at Line Output [SKU/TP] is the sum of the product/SKU units getting out of a manufacturing line over a period of time. The actual NPLO is counted or weighted at the end of the production line over the period considered.

For the budget phase, NPLO depends on the proven Batch Release Rate BRR of the site and the Expected Released Production, the term proven meaning based on previous year(s) experience.

$$BRR[\%] = 100 * \frac{Released\ Batches}{Total\ Produced\ Batches}$$

$$NPLO\left[\frac{SKU}{TP}\right] = \frac{Expected\ Released\ Production\left[\frac{SKU}{TP}\right]}{BRR[\%]}$$

3.1.2.17 Performance Rate [PR]

The Performance Rate PR [%] is the second of the three factors entering in the OEE formula. The Performance Rate is the ratio Total Production TPR (including Quality Rejects QRJ of the line) / Production Corresponding to Operating Time.

$$PR[\%] = 100 * \frac{TPR}{PCOT} = 100 * \frac{(NPLO + QRJ)}{PCOT}$$

Note: Knowing TPR and PLSS, Speed Adherence SA characterizes how much QPR is achieved in average and is calculated as follows:

$$Speed\ Adherence\ SA\ [\%] = 100 * \frac{((NPLO + QRJ) + PLSS)}{PCOT}$$

3.1.2.18 Line Output Quality Rate [LOQR]

For the purpose of OEE and performance measurement, the Line Output Quality Rate LOQR [%], which is the third and last factor required for OEE calculation, is defined as the ratio Net Production at Line Output / total production (including Quality Rejects QRJ of the line).

$$LOQR[\%] = 100 * \frac{NPLO}{TPR} = 100 * \frac{NPLO}{(NPLO + QRJ)}$$

Note: Each rejection impacts the Line Output Quality Rate. Even if part of them are reworked.

3.1.2.19 Overall Equipment Effectiveness [OEE]

Finally and as already defined at the beginning of this document, a manufacturing line OEE is the product of three factors, a) the Availability Rate, b) the Performance Rate and c) the Line Output Quality Rate.

$$OEE[\%] = \frac{1}{10\ 000} * AR[\%] * PR[\%] * LOQR[\%]$$

3.1.2.19.1 For a mono-product line, the above formula applies easily.

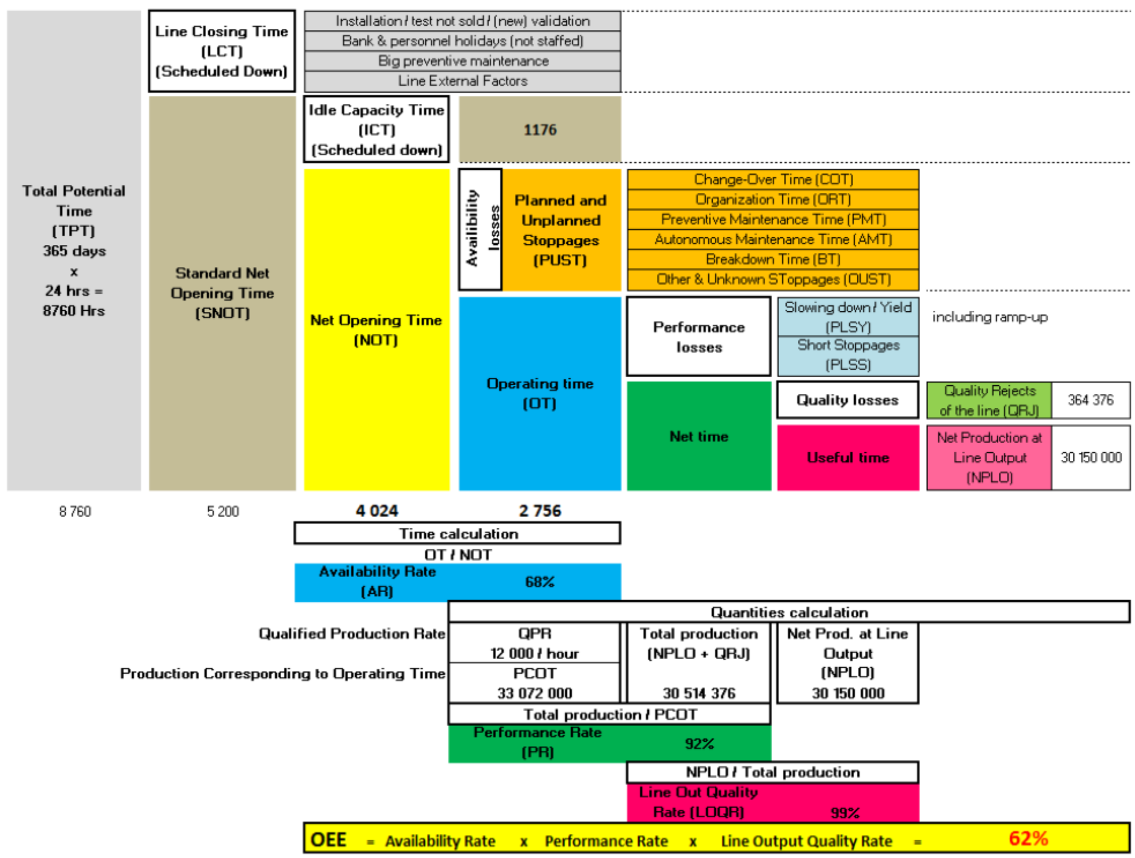

Figure 1: OEE breakdown synopsis

3.1.2.19.2 For a multi-product line (multiple SKUs), the three OEE terms are:

$$AR[\%] = 100 * \sum OTi \ / \sum NOTi$$

$$PR[\%] = 100 * \sum (NPLOi + QRJi) / \sum PCOTi$$

$$LOQR[\%] = 100 * \sum NPLOi / \sum (NPLOi + QRJi)$$

With i = 1 to n SKUs over the considered Time Period TP (shift, day, week, month, year).

							OEE of the line	Needed for Manufacturing Line Capacity calculation
Production campaigns			Presentation	Presentation	Presentation	Presentation	**TOTAL YTD**	TOTAL YTD
Presentations			Presentation 1	Presentation 3	Presentation 2	Presentation 1	**All presentations**	Presentation 1
NOT (Net Opening Time)	*here in minutes*		7200	5700	2700	4260	19860	11460
PUST (Planned & Unplanned Stoppages Time)	*here in minutes*		3052	2700	1380	1500	8632	4552
OT (Operating Time)	*here in minutes*		4148	3000	1320	2760	11228	6908
AR (**Availability Rate**) % due to PUST	OT/NOT		57,61%	52,63%	48,89%	64,79%	**56,54%**	60,28%
NPLO (Net Production at Line Output)			696 240	290 200	185 400	512 300	1 684 140	1 208 540
QRJ (Quality Rejects)			5 019	1400	1700	29100	37 219	34 119
Total production (NPLO+QRJ)	NPLO + QRJ		701 259	291600	187100	541400	1 721 359	1 242 659
QPR (Qualified Production Rate) speed	*here per minute*		**200**	**100**	**150**	**200**	**NA**	**NA**
PCOT (Production Corresponding to Operating Time)	OT x QPR		829 600	300 000	198 000	552 000	1 879 600	1 381 600
PR (**Performance Rate**) % due to short stoppages/slowing down	Total Prod / PCOT		84,53%	97,20%	94,49%	98,08%	**91,58%**	89,94%
LOQR (**Line Output Quality Rate**) %	NPLO / Total Prod		99,28%	99,52%	99,09%	94,63%	**97,84%**	97,25%
OEE (Overall Equipment Efficiency)	**AR x PR x LOQR**		**48,35%**	**50,91%**	**45,78%**	**60,13%**	**50,66%**	**52,73%**

Table 2: OEE calculation with multiple SKUs allocated to a same manufacturing line

Note: It is assumed that Change Over Time is assigned to produce the next batch.

3.1.2.20 WEIGHTED AVERAGE OEE OF A WORKSHOP WITH M LINES IN PARALLEL.

Considering that each line j [j=1 to m] consists each of n_m [i=1 to n_m] SKUs per line, the average OEE_w of that workshop is calculated using the same type of equation:

$$AR[\%] = 100 * \sum OTi,j \ / \sum NOTi,j$$

$$PR[\%] = 100 * \sum (NPLOi,j + QRJi,j) / \sum PCOTi,j$$

$$LOQR[\%] = 100 * \sum NPLOi,j / \sum (NPLOi,j + QRJi,j)$$

OEE_w is again the product of the three terms AR, PR and LOQR.

Note: Same way of calculation than on Table 2 above, taking the YTD OEE column of each line of the workshop as input, in order to calculate the YDT Workshop OEE_w.

3.1.2.21 AVERAGE OEE OF A PLANT, REGION, PLATFORM, IA

The average OEE_p of a plant with p workshops, respectively OEE_r of a region with several plants, OEE_{pl} of a platform and OEE_{IA} of Global IA will be calculated as a simple arithmetic average of the workshop in the plant, plants within the region or platform and platforms within IA.

$$OEEp(resp.r, pl, IA) = (\sum OEEw, p)/p \ (resp. s, r, pl)$$

3.1.2.22 MANUFACTURING LINE CAPACITY [MLC]

The Manufacturing Line Capacity MLC [SKU/T] is the product of the Standard Net Opening Time SNOT multiplied by the Qualified Production Rate QPR multiplied by the proven line OEE.

Note: The Standard Net Opening Time SNOT [T/YR] often considers 216.7 days or 5200 hours, which suggests operating the lines in three shifts from Monday to Friday and considering personnel working time and days off. (See table 1)

For a mono-product line, MLC is calculated as follows:

$$MLC\left[\frac{SKU\ or\ Kg}{YR}\right] = \frac{1}{100} * SNOT\left[\frac{T}{YR}\right] * QPR\left[\frac{SKU\ or\ Kg}{T}\right] * OEE[\%]$$

Example for a mono-product and mono-format pharma solids line
Potential Time = 365 days, Standard Net Opening Time = 216.7 days x 3 shifts of 8 hours = 5200 hours
Qualified Production Rate = 5000 boxes per hour (line nominal speed for SKU considered), OEE=50.3%,
MLC [Boxes/Year] = 5200 [hours] x 5000 [Boxes/hour] x 0.503 = 13 078 000 Boxes/Yr

In reality, there are many manufacturing lines, such as tabletting, filling, packaging which are not dedicated only to a single product or SKU but to several. The MLC must in this case be calculated as the weighted average of the various products or SKUs.

For budget and planning purposes, assumptions must be taken for the MLC calculation, such as number and quantity of products, formats and SKUs to be manufactured on that line over the considered Time Period TP (ex: the year), and a model must calculate the time required to manufacture each product, format SKU and estimate the corresponding Change-Over Times COT.

For multi-product/format line, MLC is calculated as follows:

$$MLC\ [SKU/YR] = SNOT * \frac{\sum_{i=1}^{n} NPLO(i)}{\sum_{i=1}^{n} RNOT(i)}$$

Where a) i = 1 to n SKUs, b) NPLO(i) are the numbers of SKUs to produce, c) Required Net Opening Time [RNOT] (i) = $\mathrm{NPLO(i)/(QPR(i) * OEE(i))}$, Standard Net Opening Time SNOT=216.7 days or 5200 hours or the value to be used over the period considered.

	MLC					SNOT
	[6] 24 181 441					[1] 5 200
Portfolio products	NPLO Y+1	Qualified Prod Rate/Hour	proven line OEE [1]	RNOT (hrs)		CUF
SKU 1	[1] 8 350 000	12000	55%	[2] 1265		[3] 24,3%
SKU 2	5 950 000	9000	49%	1349		25,9%
SKU 3	3 750 000	6000	45%	1389		26,7%
SKU 4	2 450 000	10800	56%	405		7,8%
Total	[5] 20 500 000			[5] 4 408		[4] 84,8%

Table 3: MLC calculation according to products portfolio (from [1] input data to [6] output data)

3.1.2.23 Capacity Utilization Factor [CUF]

The Capacity Utilization Factor CUF [%] is the ratio between the sum of NPLO(i) (budget phase or actually produced at year end) and its Manufacturing Line Capacity MLC considering the related SKUs portfolio. It can also be calculated by the ratio of the sum of Required Net Opening Time (i) / SNOT

$$CUF\ [\%] = 100 * \frac{\sum NPLO(i)}{MLC} = 100 * \frac{\sum RNOT(i)}{SNOT}$$

When the Capacity Utilization Factor of a line exceeds 85%, Management has to review the potential to increase the Net Opening Time and/or the OEE and/or the QPR, or its site/platform manufacturing capacity planning and investment strategy as the considered manufacturing line may not produce any additional volume in a sustainable manner.

Note 1: CUF [%] based on **SNOT of 5200 Hours is used in the Strat Plan for Drug Products manufacturing lines** to calculate the **Pharma's KPI Capital Productivity [%] = CUF [%] x OEE [%]**
(Here the CUF [%] could be above 100% depending on the requested NOT)

Note 2: CUF [%] based on **SNOT of 8760 hours (TPT) is used in the Strat Plan for Drug Substances manufacturing lines** to calculate the KPI Capital Productivity [%]. In this case only, CUF [%] equal LOR [%] because Occupancy rate is based on TPT as described in chapter 3.1.2.8. Therefore, the **continuous manufacturing's KPI Capital Productivity [%] = LOR [%] x OEE [%]**

3.1.2.24 Technical Downtime [TD]

Technical Downtime TD [%] is a maintenance KPI and is defined as the ratio between the sum of Maintenance Times, Breakdowns Time and the Net Opening Time minus Change-Over Time, Organisation Time and Other & Unknown Stoppages Time. The Big Preventive Maintenance Time BPMT is not considered in the sum of Maintenance Times.

$$TD\ [\%] = 100 * \frac{AMT + PMT + BT}{\ldots}$$

3.2 LINES CAPACITY, PRODUCTION PLANNING AND OEE MANAGEMENT

Sites Leadership must implement Manufacturing Lines Capacity and OEE management at all manufacturing lines and in particular on critical ones.

3.2.1 BUDGET PHASE AND PRODUCTION PLANNING

During the budget preparation phase, Manufacturing Lines Capacities (MLCs) must be rechecked and possibly recalculated in function of the products/SKUs portfolio, Qualified Production Rates QPR, OEE component's assumptions and Batch Release Rate BRR. Formulas defined above must be used.

Production planning must ensure that volumes to be produced can be satisfied, i.e. these volumes are lower than MLCs. The planning phase determines the adjustment of Idle Capacity Time ICT.

When the budget is prepared, the Expected Released Production must be incremented by the factor 1/BRR to define the targeted NPLO defined in the chapter 3.1.2.16 in order to account for the total quality rejects.

3.2.2 PRODUCTION PHASE

A data management system must be implemented to track all the data allowing the determination and calculation of the Net Opening Time, Availability Rate, Performance Rate, Line Output Quality Rate, OEE, Technical Downtime and actual production volumes.

These data must be captured for each shift and resulting indicators (NOT, AR, PR, LOQR, OEE) may be displayed daily, weekly, monthly and yearly and compared to budget targets. Twelve months rolling average is recommended to compare actual OEE against annual budgeted OEE.

3.3 APPLICATION CASES

3.3.1 SEQUENTIAL PRODUCTION PROCESS

Sequential production process applies well to tableting, filling, packaging and to some batch production in chemical and biologics processes where a new batch is not launched before the previous one is finished and left the line. The diagram below illustrates sequential production.

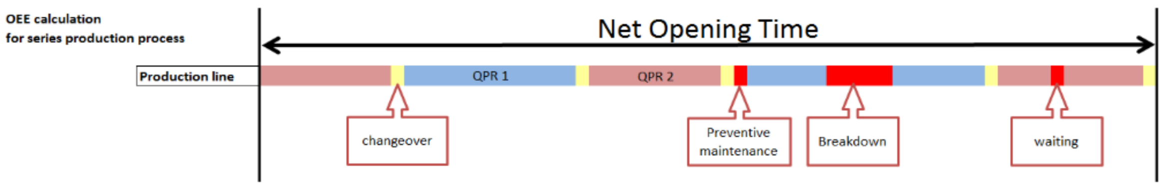

Figure 2: Stoppages impacting OEE calculation on a sequential production line

3.3.2 MASKED TIME PRODUCTION PROCESS

When a production process is not sequential, which means that a product batch production may be initiated before the previous left the production line (ex USP or DSP in Biologics), with several masked time production steps, it may be more difficult to model the process and determine the way to calculate OEE and MLC.

For example, batch or fed-batch processes show some de-coupling of the various process steps realized by holding steps, i.e. buffer tank (in liquid phase), silo, dryer or similar temporary storage (wet or dry) to cover varying batch size.

Such situations can be used for both corrective/curative (planed or non-planed) or preventive (scheduled) maintenance works or calibration (scheduled) activities without jeopardizing the line availability.

Therefore, in masked time production processes, the OEE calculation will be made considering only the step which represents the bottleneck of the production unit or line (ex. Equipment F in the figure below).

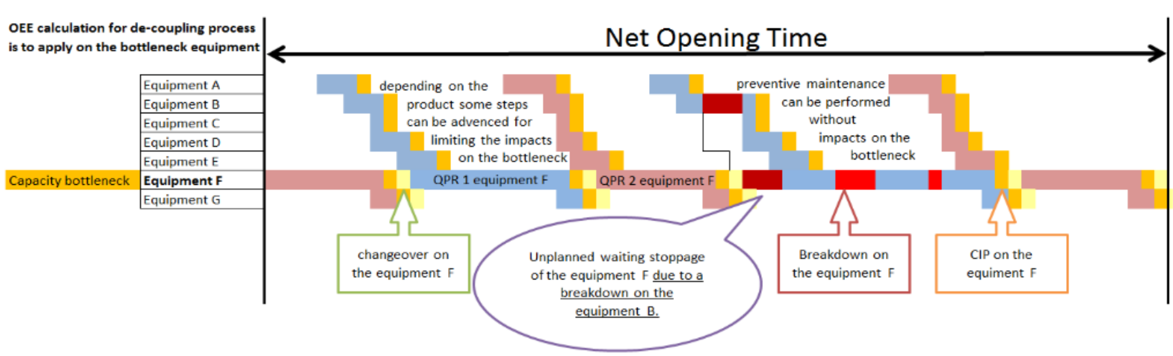

Figure 3: Stoppages impacting OEE calculation on a masked time production process

3.4 REAL-TIME DATA ACQUISITION SYSTEMS

Data can be captured manually on notebooks, data sheets for each manufacturing line and then captured on excel sheets to calculate the resulting indicators. They may also be acquired automatically by the manufacturing line's process control systems or sensors coupled to calculation algorithms.

Automated data acquisition is recommended over manual data capture as it relieves operators and supervisors from this task and allows better data reliability than manual data management, in particular for short stoppages which are difficult to track.

These data also allow calculation of other statistics and indicators not defined in this document, such as Stoppages statistics, Mean Time Between Failure, Mean Time To Repair, etc. Databases allow retrieving data for subsequent analysis.

3.4.1 DATA TO BE CAPTURED ON A SEQUENTIAL PRODUCTION PROCESS LIKE A PACKAGING LINE

For a packaging line, from thermoforming to the line end there is most of the time no buffer and each step influences the next one's output, so it means that data have to be collected on this part of the line. While, whatever the product managed by the line, the steps before the thermoforming/cartoning have most of the time buffers for syringes, vials, tablets or also pens…

Regarding the data to be collected as minimum for eOEE calculation (even if reasons/categories may remain manually selected), beside scheduled shutdowns which clarify when the line is open and staffed for production activities (NOT) as well as ongoing production's master data (QPR, blister per box, boxes per shipper), the two below functions have to be delineated:

- the line's status which can be reflected by the bottleneck machine's status itself (thermoforming machine most of the time or cartoning, as there is then no buffer)
  - Planned and Unplanned Stoppage Time of the bottleneck machine > 2 minutes is the PUST (or greater than a max time considered for instance to unblock a situation: short stops time)
  - Short stops time of the bottleneck machine < 2 minutes is the SST
- the counting function related to the "good" products at the end of the line included in good shippers is the NPLO

Note: All rejected quantities from the thermoforming machine to the end of the line (QRJ), may be declared manually or captured in order to avoid mixing performance and quality losses. Even if OEE rate is not affected, improvements can be achieved thanks to an analysis on stratifications of losses categories. In other words, if rejections from Thermoforming to the end of the line are not known by the eOEE system, all deduced missing boxes at the line end's count, compared to the PCOT will be wrongly interpreted as slowing down (PLSY), while LOQR would be wrongly shown at 100%.

Function Analysis System Technic for Packaging line

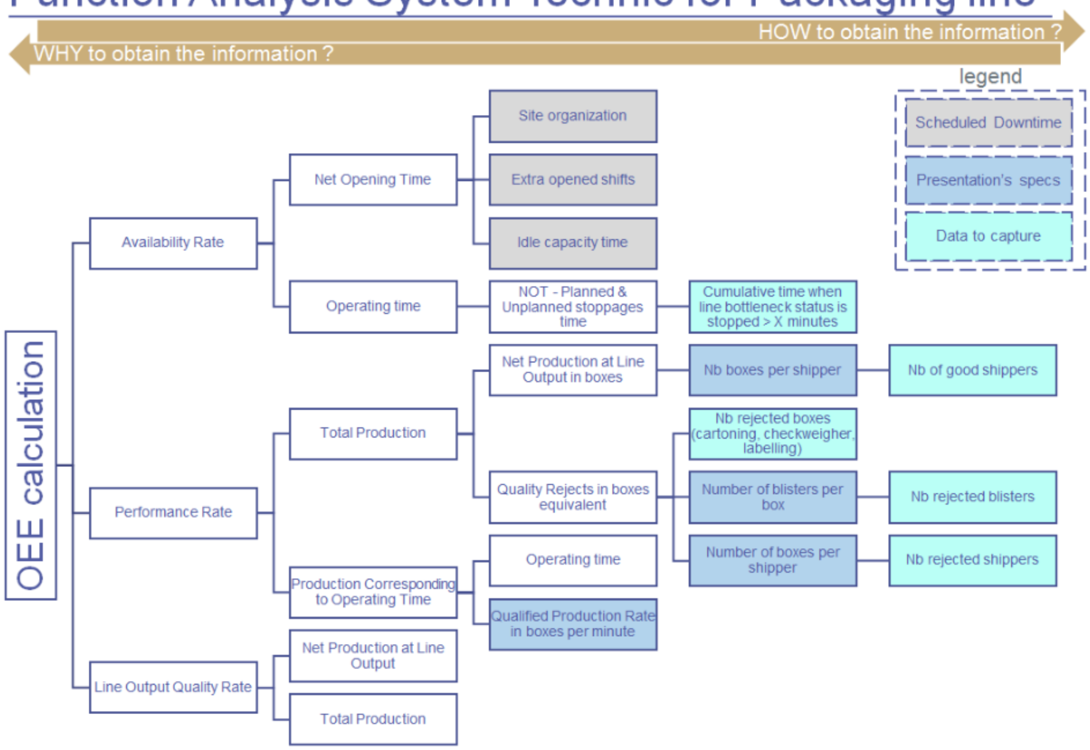

Figure 4: Functional Analysis showing data needed for a packaging line

eOEE software calculation features example for Packaging

Time considered with the same presentation (1 week = 10 080 minutes & QPR of 200 boxes/min)

Inputs

Calculations

						categorization												
Data captured	Line status	Stoppage duration auto sorting	cumulated time (minutes)	nb of short stops	PLSS	Scheduled down	PUST sub-categories	Operating Time	NOT	Captured quantities	TPR Converted in boxes	PCOT	speed adherence	PLSY	QR	PR	AR	OEE
Line bottleneck machine status	stopped	> x minutes	5932			2880			removed									
							3052		7200								57,61%	
		short stops	324	972	64800			4148				829600				84,53%		
	running		3824										92%	63541				
blisters rejected										4898	2449							
boxes rejected										573	573							48,35%
checkweiher rejections										77	77				99,28%			
shipper rejected										24	1920							
good shippers										8703	696240							
TOTAL			10080								701259							

presentation specifications		
Blisters/box	boxes QPR	boxes/shipper
2	200	80

Automatically captured from ERP would be a major help for accurate eOEE and operator's manual inputs avoidance

Table 4 : Example using data to be captured on a packaging line

3.5 DATA ANALYSIS AND PERFORMANCE MANAGEMENT

The set of data and indicators allow for a detailed analysis of planning and production processes by first setting assumptions for the manufacturing targets during the budget phase (Days for Net Opening Time, planned and unplanned stoppages based on experience of previous years, etc.) and then analysing what really happened during the year by comparing indicators against their budgeted value.

SANOFI IA - OEE CALCULATION SHEET - (*EXAMPLE*)

			YEARLY BUDGET PREPARATION PHASE				ACTUAL PERFORMANCE AT YEAR END			
Case:	PACKAGING EXAMPLE									
Date:	12/12/2018									
Prepared by:	EH									
	TOTAL POTENTIAL TIME (TPT):	Unit	data	Days (or hours or Qty)	order to fill	Assumptions and Comments for Budget phase	data	Days (or hours or Qty)	order to fill	Comments year end
		Day		365,0				365,0		
Scheduled down time	Bank Holidays Time (BHT)	Day	input	112,0	1	Saturdays, Sundays and public holidays	input	109,0	1	3 Saturdays needed
	Big Preventive Maintenance Time (BPMT)	Day	input	20,0	1	General plant shutdown impairing manufacturing	input	22,0	1	Two days more for BPMT
	Personnel Holidays Time (PHT)	Day	input	11,0	1	Part not placed during BPMT and personnel not replaced	input	14,0	1	3 days more than forecasted
	New Products Development Time (NPDT)	Day	input	10,0	1	New machine validation	input	12,0	1	2 days delay
	External Factors Down Time (EFDT)	Day	input	0,0	1		input	1,9	1	power supply
	Total Line Closing Time (LCT)	Day	BHT+BPMT+PHT+NPDT	153,0			BHT+BPMT+PHT+NPDT+Other	158,9		
	Shifts opened per day	Nb	input	3,0	1		input	3,0	1	
	Hours per shift	Hours	input	8,0	1		input	8,0	1	
	STANDARD NET OPENING TIME (SNOT):	Hours	(TPT-LCT)*Shifts*Shift	5088,0			(TPT-LCT)*Shifts*Shift hours	4946,4		Actual potential opening time
	Idle Capacity Time (ICT)	Hours	((TPT-LCT)*24)-NOT	987,4			((TPT-LCT)*24)-NOT	581,4		
	Total Scheduled Down Time (SDT)	Hours	(LCT*24)+ICT	4659,4		LINE OCCUPATION RATE (LOR) = NOT/TPT	(LCT*24)+ICT	740,3		LINE OCCUPATION RATE (LOR) = NOT/TPT
	NET OPENING TIME:	Hours	OT+PUST	4100,6		46,8%	input	4365,0	3	49,8%
Planned and unplanned stoppages	Change-Over Time (COT)	Hours	input	552,0	4	SMED roll-out & training	input	734,0	4	Better than previous year but not at budget
	Organization Time (ORT)	Hours	input	148,0	4	Kanban implementation	input	172,0	4	Higher absenteeism than budgeted
	Autonomous Maintenance Time (AMT)	Hours	input	108,5	4	Continuing TPM roll-out	input	87,0	4	
	Preventive Maintenance Time (PMT)	Hours	input	86,0	4	try to do more during BPMT	input	96,0	4	
	Breakdown Time (BT)	Hours	input	586,0	4	Assumption based on previous year	input	602,0	4	Better than previous year but not at budget
	Other/Unknown SToppages (OUST) (< 10% PUST)	Hours	input	110,0	4	Other stoppage time not listed above	input	87,0	4	
	Total Planned and Unplanned Stoppages Time (PUST)	Hours	COT+ORT+AMT+PMT+BT+OUST	1590,5		AVAILABILITY RATE (AR) = OT/NOT	COT+ORT+AMT+PMT+BT+OUST	1778,0		AVAILABILITY RATE (AR) = OT/NOT
	OPERATING TIME (OT):	Hours	(TPLO+QRJ+NPLO)/QPR	2510,1		61,2%	NOT-PUST	2587,0		59,3%
	Production Corresp. to Oper. Time (PCOT):	Qty	OT*QPR	30 120 833			OT*QPR	31 044 000		
Performance Losses	Losses due to Slowing down or Yield (PLSY)	Qty	input	1 100 000	4	Action to update SOPs with settings allowing QPR	PCOT-PLSS-QRJ-NPLO	3 716 506		
	Losses due to Short Stoppages (PLSS)	Qty	input	2 300 000	4	Assumptions taken for Budget based on last year perf.	input	324 987	7	Cumulated Short Stoppage Time x QPR or Estimate
	Total Performance Losses (TPLO)	Qty	PLSY+PLSS	3 400 000		PERFORMANCE RATE (PR) = TPR/PCOT	PLSY+PLSS	4 041 493		PERFORMANCE RATE (PR) = TPR/PCOT
"Net time" Equivalent	Total PRoduction (TPR)	Qty	NPLO+QRJ	26 720 833		88,7%	NPLO+QRJ	27 002 507		87,0%
Quality	Total Quality Rejects at line level (QRJ)	Qty	input	1 200 000	4	LINE OUTPUT QUALITY RATE (LOQR) =	input	1 354 653	6	LINE OUTPUT QUALITY RATE (LOQR) =
"Useful time" Equivalent	NET PRODUCTION AT LINE OUTPUT (NPLO)	Qty	Expected released prod BRR%	25 520 833		95,5%	input	25 647 854	5	95,0%
	Historical Batch Release Rate BRR		input	96,0%	3	OEE (ARxPRxLOQR)				OEE (ARxPRxLOQR)
	EXPECTED AND ACTUAL RELEASED PRODUCTION:	Qty	input	24 500 000	3	51,9%				49,0%
			NPLO/MLC			BUDGETED CAPACITY UTILIZATION FACTOR	NPLO/MLC			ACTUAL CAPACITY UTILIZATION FACTOR
	QUALIFIED PROD. RATE QPR (UNITS / HR):	SpeedHour	input	12 000	2	80,6%	input	12 000	2	85,8%
	MANUFACTURING LINE CAPACITY (at SNOT):	Qty				31 666 334				29 896 055
	Technical Downtime (TD) = [(AMT+PMT+BT) / (NOT-(COT+ORT+OUST))]					23,7%				23,3%

Table 5: Example monopres line budget sheet included in the SD-000109 workbook

Pareto analysis of planned and unplanned stoppages, performance losses and quality rejects must be implemented along these manufacturing steps.

Continuous improvement plan must be built based on regular analysis of the evolution of these main KPIs, as well as the evolution of the availability loss categories (PUST). Moreover, to distinguish the unplanned stoppages from the planned activities ease the identification and selection of the few most recurrent and important unexpected time loss subcategories, which have to be investigated and improved as a priority. On the other hand, to regularly compare the standard duration defined for planned activities with their actual value allows to improve, reassess and sustain them over time.

4. RESPONSIBILITIES

The manufacturing Site's leadership team members, IA platforms Management are responsible to implement this Standard.

Global IA Manufacturing Excellence is responsible to periodically maintain and update this Standard according to the business needs.

5. REFERENCES

NA

6. DEFINITIONS

Please refer to the chapter 3.1 Definitions and associated requirements.

7. APPENDICES

SD-000109 SANOFI IA OEE CALCULATION WORKBOOK in its applicable version.

SANOFI IA - OEE LINE CALCULATION SHEET Multi SKUs *(Example)*

Presentations managed on the line	QPR (units/hour)
2srg	9 000
6 srg	3 000
10 srg	1 800

Line	Line C6
Last update	30/11/2018

Template from:	Global IA - ME - Engineering and Maintenance
Date:	JUNE 2019
Revision:	3
Contact:	Emeric HOLASZ

Presentation	end of the production campaign	QUALIFIED PROD. RATE QPR (UNITS / HR)	NET OPENING TIME	Planned and unplanned stoppages: Change-Over Time (COT)	Organization Time (ORT)	Autonomous Maintenance Time (AMT)	Preventive Maintenance Time (PMT)	Breakdown Time (BT)	Other/Unknown STOppages (OUST) < 10% PUST	Total Planned and Unplanned Stoppages Time (PUST)	OPERATING TIME (OT)	AVAILABILITY RATE (AR)	Production Corresp. to Oper. Time (PCOT)
Presentation	last week	Speed/Hour	Hours	Hours	Hours	Hours	Hours	Hours	Hours	Hours	Hours	%	Qty
Line C6	YTD	N/A	7 234	960	223	122	157	1 736	46	3 244	3 990	55,2%	13 328 400
2srg	YTD	9 000	1 136	148	33	21	41	166	46	455	681	59,9%	6 129 000
6 srg	YTD	3 000	1 621	232	50	32	16	255		585	1 036	63,9%	3 108 000
10 srg	YTD	1 800	4 477	580	140	69	100	1 315		2 204	2 273	50,8%	4 091 400
	YTD	#N/A											-
	YTD	#N/A											-
	YTD	#N/A											-
	YTD	#N/A											-
	YTD	#N/A											-
	YTD	#N/A											-
2srg	1	9 000	96	4	1			23		28	68	70,8%	612 000
6 srg	3	3 000	215	24	9	2	3	45		83	132	61,4%	396 000
10 srg	4	1 800	167	16	8	4	2	36		66	101	60,5%	181 800
6 srg	9	3 000	552	76	14	8	6	76		180	372	67,4%	1 116 000
2srg	18	9 000	1 040	144	32	21	41	143	46	427	613	58,9%	5 517 000
10 srg	36	1 800	4 310	564	132	65	98	1 279		2 138	2 172	50,4%	3 909 600
6 srg	48	3 000	854	132	27	22	7	134		322	532	62,3%	1 596 000

Presentation	Speed adherence	Performance Losses: Losses due to Slowing down or Yield (PLSY)	Losses due to Short Stoppages (PLSS)	Time loss due to Short Stoppages	Total Performance Losses (TPLO)	"Net time" Equivalent: Total PRoduction (TPR)	PERFORMANCE RATE (PR)	Quality Losses: Total Quality Rejects at line level (QRJ)	"Useful time" Equivalent: NET PRODUCTION AT LINE OUTPUT (NPLO)	LINE OUTPUT QUALITY RATE (LOQR)	OEE	Technical Downtime (TD)
Presentation	%	Qty	Qty	Hours	Qty	Qty	%	Qty	Qty	%		%
Line C6	N/A	1 780 959	129 434	27,0	1 910 393	11 418 007	85,7%	249 145	11 168 862	97,8%	46,2%	33,6%
2srg	79,1%	1 260 796	97 086	10,8	1 357 882	4 771 118	77,8%	48 219	4 722 899	99,0%	46,2%	25,1%
6 srg	92,2%	242 851	8 127	2,7	250 978	2 857 022	91,9%	104 604	2 752 418	96,3%	56,6%	22,6%
10 srg	93,2%	277 312	24 221	13,5	301 533	3 789 867	92,6%	96 322	3 693 545	97,5%	45,8%	39,5%
		-	-		-	-		-	-			
		-	-		-	-		-	-			
		-	-		-	-		-	-			
		-	-		-	-		-	-			
		-	-		-	-		-	-			
		-	-		-	-		-	-			
2srg	99,4%	3 350	9 786	1,1	13 136	598 864	97,9%	321	598 543	99,9%	69,3%	25,3%
6 srg	94,8%	20 534	3 456	1,2	23 990	372 010	93,9%	43 654	328 356	88,3%	50,9%	27,5%
10 srg	99,3%	1 121	14 356	8,0	15 477	166 323	91,5%	9 537	156 786	94,3%	52,2%	29,4%
6 srg	92,9%	79 512	1 426	0,5	80 938	1 035 062	92,7%	56 387	978 675	94,6%	59,1%	19,5%
2srg	76,8%	1 257 446	87 300	9,7	1 344 746	4 172 254	75,6%	47 898	4 124 356	98,9%	44,1%	25,1%
10 srg	92,9%	276 191	9 865	5,5	286 056	3 623 544	92,7%	86 785	3 536 759	97,6%	45,6%	39,9%
6 srg	91,0%	142 805	3 245	1,1	146 050	1 449 950	90,8%	4 563	1 445 387	99,7%	56,4%	23,5%

8. DOCUMENT HISTORY

Version Number	Version Application Date	Description of change
1.0	01-Oct-18	Initial version gathering improved Sanofi IA SMS practice.
1.0	16-Sept-19	Acronyms chapter (3.1.1) Standard Net Opening Time is 5200 hours in Pharma and 8760 Hours in Chemistry & Biologics (3.1.2.4 notes 1 & 2) Consistency of QRJ with NPLO's unit (3.1.2.15 note 2) Speed Adherence ratio (3.1.2.17 note) The Capital Productivity KPI (3.1.2.23 notes 1 & 2) Data to be captured on a sequential production process like a packaging line (3.4.1) Additional explanation on how to analyse data for identifying improvement priorities (3.5) Migration from GDOPS-014365 Version 1 to STD-000030 Version 1 Implementation of the new template STD Additional examples and templates in the supporting document workbook SD-000109
2.0		Correction of the table of content pagination

Specificities

Global Industrial Technology		
4 - Plan To Manufacture		4.2 - Equipment Facilities & Management
IT - General Equipment	No Subsystem	No Subsystem

Applicability

Entity / GBU	Sanofi Company		

Geography	Worldwide		

Applications Services	Industrial Affairs	Industrial Technology	

Supporting document

Reference	Title
SD-000109	SANOFI IA – OEE CALCULATION SHEET

Migration Number	GDOPS-014365