CORVANE BIOLOGICS

Filling line FL-5 — production schedule and OEE

First quarter 2026 (ISO weeks 1–13, 29.12.2025 – 29.03.2026) · Industriezone Rottenmatte



Status date lun 23.03.2026 *Change the status date to move the marker on the Gantt chart.*

Key figures

Campaigns completed	Good units, weeks 1–12	OEE Q1	Availability	Line occupancy	EM action-level results
31	2 418 363	81,1%	90,0%	71%	1

Quarter by product family

Family	Campaigns	Vials planned	Good units	Line hours	Share of hours	Service value
Monoclonal antibodies – vials	15	1 321 000	1 216 193	630	40,7%	CHF 1 794 243
Enzymes and fusion proteins – vials	8	380 000	343 017	346	22,4%	CHF 986 015
Prefilled syringes – RTU nests	9	864 000	859 154	399	25,8%	CHF 1 135 945
Line activities	2	40 000	0	171	11,1%	CHF 487 192
Total	**34**	**2 605 000**	**2 418 364**	**1 545**	**100%**	**CHF 4 403 395**

Contents

Gantt	Daily Gantt chart, 13 weeks, bars by conditional formatting, row groups by family
Campaigns	Campaign chain as Excel table with durations [h]:mm and total row
OEE by week	Availability, performance, quality and OEE with colour scales
Downtime Pareto	Sorted Pareto with cumulative share and the MES event log
EM heat map	Grade A/B particle heat map and viable monitoring
Shift roster	Roster weeks 6–9, staffing checks, shift times and skills matrix
Charts	Stock, radar, bubble and stacked-area charts
Notes	Rules, definitions, abbreviations

Highlights of the quarter

- OEE weeks 1–12: 81.1 % against the site target of 72 %; availability 90.0 %, performance 90.8 %, quality 99.25 %.
- Largest loss: stopper feed / bowl jam (19 % of unplanned downtime); a weekly bowl-amplitude check was added to SOP FL5-OP-12.
- Annual shutdown in week 5 completed on plan and followed by the aseptic process simulation APS-26-1 (three runs, no contaminated units).
- One Grade A action-level particle result on 04.02.2026 during a needle change (DEV-26-0042, 1 CFU active air); the assessment concluded no impact on the batch.
- 2 campaigns are planned or in progress after the status date; the quarter closes with a line occupancy of 71 %.

Production schedule FL-5 — Gantt chart Q1 2026

◂ Overview

Bars are drawn by conditional formatting from the campaign start and end (Campaigns table); weekends shaded; red frame = status date

Campaign	Product	Start	End	Hours	Status
Monoclonal antibodies – vials · 15 campaigns					
C26-01	CVB-0217	29.12. 15:00	31.12. 11:42	44:42	Completed
C26-02	NVL-204	01.01. 02:42	02.01. 16:15	37:33	Completed
C26-06	CVB-0388	11.01. 13:08	13.01. 05:23	40:15	Completed
C26-07	CVB-0217	13.01. 11:23	15.01. 11:21	47:57	Completed
C26-09	NVL-204	19.01. 03:56	20.01. 22:42	42:45	Completed
C26-12	CVB-0388	03.02. 12:03	05.02. 10:03	45:59	Completed
C26-14	CVB-0217	08.02. 10:24	10.02. 03:38	41:14	Completed
C26-15	NVL-204	11.02. 12:38	13.02. 00:47	36:09	Completed
C26-19	CVB-0217	21.02. 15:09	23.02. 13:57	46:48	Completed
C26-21	CVB-0388	26.02. 13:37	28.02. 04:56	39:18	Completed
C26-22	NVL-204	28.02. 13:56	02.03. 03:50	37:53	Completed
C26-25	CVB-0217	07.03. 20:01	09.03. 17:43	45:42	Completed
C26-27	NVL-204	12.03. 15:53	14.03. 04:05	36:11	Completed
C26-28	CVB-0388	14.03. 19:05	16.03. 12:26	41:21	Completed
C26-31	CVB-0217	22.03. 12:08	24.03. 09:48	45:40	In progress
Enzymes and fusion proteins – vials · 8 campaigns					
C26-03	ENZ-061	03.01. 13:15	05.01. 09:10	43:54	Completed
C26-08	FPR-918	16.01. 17:21	18.01. 13:56	44:35	Completed
C26-10	ENZ-061	21.01. 22:42	23.01. 14:58	40:15	Completed
C26-16	FPR-918	13.02. 18:47	15.02. 14:42	43:54	Completed
C26-18	ENZ-061	18.02. 14:35	20.02. 12:09	45:33	Completed
C26-24	ENZ-061	05.03. 11:41	07.03. 08:01	44:19	Completed
C26-30	FPR-918	19.03. 13:58	21.03. 09:08	43:09	Completed
C26-32	ENZ-061	25.03. 00:48	26.03. 17:03	40:15	Planned
Prefilled syringes – RTU nests · 9 campaigns					
C26-04	CVB-0217S	05.01. 21:10	07.01. 21:54	48:44	Completed
C26-05	HPX-077	09.01. 00:54	10.01. 19:08	42:13	Completed
C26-11	CVB-0217S	24.01. 05:58	26.01. 03:06	45:08	Completed
C26-13	HPX-077	06.02. 01:03	07.02. 22:24	45:21	Completed
C26-17	CVB-0217S	15.02. 23:42	17.02. 23:35	47:52	Completed
C26-20	HPX-077	24.02. 01:57	25.02. 19:37	41:40	Completed
C26-23	CVB-0217S	02.03. 18:50	04.03. 14:41	43:51	Completed
C26-26	HPX-077	10.03. 11:43	12.03. 03:53	40:09	Completed
C26-29	CVB-0217S	17.03. 00:26	18.03. 19:58	43:32	Completed
Line activities · 2 campaigns					
PM-26-1	PM	26.01. 12:06	01.02. 00:06	132:00	Completed
APS-26-1	APS	01.02. 00:06	02.02. 15:03	38:56	Completed



Line occupancy (hours per day)

Occupancy in % of calendar time (quarter) **70,7%**

Legend

- CVB-0217 – CVB-0217 100 mg/4 mL
- CVB-0388 – CVB-0388 400 mg/8 mL
- NVL-204 – NVL-204 50 mg/1 mL
- ENZ-061 – ENZ-061 enzyme 5 mL
- FPR-918 – FPR-918 fusion protein
- CVB-0217S – CVB-0217 SC 1 mL PFS
- HPX-077 – HPX-077 2.25 mL PFS
- APS – Aseptic process simulation
- PM – Planned maintenance & requalification
- Weekend
- Status date (named range StatusDate)

Campaign plan FL-5 (Excel table)

◂ Overview

Chronological campaign chain: each start = previous end + waiting time; filling time from vials and nominal speed (planning factor 80 %), actual MES values for completed campaigns

Campaign	Product	Family	Client	Batches	Container	Vials planned	Fill mL	Speed	Waiting	Start	Setup	Filling	Cleaning	End	Duration	Good vials	OEE	Service value	Status
C26-01	CVB-0217	Monoclonal antibodies – vials	Corvane (internal)	3	6R vial	99 000	4,0	120	9:00	29.12.25 15:00	22:00	15:42	7:00	31.12.25 11:42	44:42	98 506	87,1%	CHF 127 399	Completed
C26-02	NVL-204	Monoclonal antibodies – vials	Client C-014	2	2R vial	105 000	1,0	180	15:00	01.01.26 02:42	20:00	11:33	6:00	02.01.26 16:15	37:33	104 627	83,8%	CHF 107 040	Completed
C26-03	ENZ-061	Enzymes and fusion proteins – vials	Client C-031	2	6R vial	57 000	5,0	110	21:00	03.01.26 13:15	26:00	9:54	8:00	05.01.26 09:10	43:54	56 295	86,0%	CHF 125 155	Completed
C26-04	CVB-0217S	Prefilled syringes – RTU nests	Corvane (internal)	3	1 mL long syringe	135 000	1,0	200	12:00	05.01.26 21:10	28:00	13:44	7:00	07.01.26 21:54	48:44	134 972	81,9%	CHF 138 902	Completed
C26-05	HPX-077	Prefilled syringes – RTU nests	Client C-009	2	2.25 mL syringe	78 000	2,0	160	27:00	09.01.26 00:54	24:00	11:13	7:00	10.01.26 19:08	42:13	77 826	72,2%	CHF 120 356	Completed
C26-06	CVB-0388	Monoclonal antibodies – vials	Corvane (internal)	2	10R vial	45 000	8,0	90	18:00	11.01.26 13:08	22:00	10:15	8:00	13.01.26 05:23	40:15	44 629	80,6%	CHF 114 722	Completed
C26-07	CVB-0217	Monoclonal antibodies – vials	Corvane (internal)	3	6R vial	108 000	4,0	120	6:00	13.01.26 11:23	22:00	18:57	7:00	15.01.26 11:21	47:57	107 863	79,0%	CHF 136 683	Completed
C26-08	FPR-918	Enzymes and fusion proteins – vials	Client C-022	2	10R vial	51 000	6,0	95	30:00	16.01.26 17:21	26:00	10:35	8:00	18.01.26 13:56	44:35	50 335	83,4%	CHF 127 078	Completed
C26-09	NVL-204	Monoclonal antibodies – vials	Client C-014	3	2R vial	144 000	1,0	180	14:00	19.01.26 03:56	20:00	16:45	6:00	20.01.26 22:42	42:45	142 145	78,5%	CHF 121 869	Completed
C26-10	ENZ-061	Enzymes and fusion proteins – vials	Client C-031	1	6R vial	32 000	5,0	110	24:00	21.01.26 22:42	26:00	6:15	8:00	23.01.26 14:58	40:15	31 595	76,4%	CHF 114 756	Completed
C26-11	CVB-0217S	Prefilled syringes – RTU nests	Corvane (internal)	2	1 mL long syringe	90 000	1,0	200	15:00	24.01.26 05:58	28:00	10:08	7:00	26.01.26 03:06	45:08	88 794	72,9%	CHF 128 664	Completed
PM-26-1	PM	Line activities	Engineering	0	–	0	0,0	1	9:00	26.01.26 12:06	132:00	0:00	0:00	01.02.26 00:06	132:00			CHF 376 200	Completed
APS-26-1	APS	Line activities	Corvane QA	3	2R / 10R vial	40 000	1,0	120	0:00	01.02.26 00:06	24:00	6:56	8:00	02.02.26 15:03	38:56			CHF 110 992	Completed
C26-12	CVB-0388	Monoclonal antibodies – vials	Corvane (internal)	3	10R vial	68 000	8,0	90	21:00	03.02.26 12:03	24:00	13:59	8:00	05.02.26 10:03	45:59	67 259	89,0%	CHF 131 086	Completed
C26-13	HPX-077	Prefilled syringes – RTU nests	Client C-009	3	2.25 mL syringe	117 000	2,0	160	15:00	06.02.26 01:03	24:00	14:21	7:00	07.02.26 22:24	45:21	115 438	83,7%	CHF 129 277	Completed
C26-14	CVB-0217	Monoclonal antibodies – vials	Corvane (internal)	2	6R vial	72 000	4,0	120	12:00	08.02.26 10:24	22:00	12:14	7:00	10.02.26 03:38	41:14	71 412	81,1%	CHF 117 520	Completed
C26-15	NVL-204	Monoclonal antibodies – vials	Client C-014	2	2R vial	96 000	1,0	180	33:00	11.02.26 12:38	20:00	10:09	6:00	13.02.26 00:47	36:09	94 926	86,6%	CHF 103 032	Completed
C26-16	FPR-918	Enzymes and fusion proteins – vials	Client C-022	2	10R vial	48 000	6,0	95	18:00	13.02.26 18:47	26:00	9:54	8:00	15.02.26 14:42	43:54	47 452	84,0%	CHF 125 150	Completed
C26-17	CVB-0217S	Prefilled syringes – RTU nests	Corvane (internal)	3	1 mL long syringe	126 000	1,0	200	9:00	15.02.26 23:42	28:00	12:52	7:00	17.02.26 23:35	47:52	125 869	81,4%	CHF 136 457	Completed
C26-18	ENZ-061	Enzymes and fusion proteins – vials	Client C-031	2	6R vial	60 000	5,0	110	15:00	18.02.26 14:35	26:00	11:33	8:00	20.02.26 12:09	45:33	59 456	77,9%	CHF 129 859	Completed
C26-19	CVB-0217	Monoclonal antibodies – vials	Corvane (internal)	3	6R vial	104 000	4,0	120	27:00	21.02.26 15:09	22:00	17:48	7:00	23.02.26 13:57	46:48	102 748	80,1%	CHF 133 400	Completed
C26-20	HPX-077	Prefilled syringes – RTU nests	Client C-009	2	2.25 mL syringe	75 000	2,0	160	12:00	24.02.26 01:57	24:00	10:40	7:00	25.02.26 19:37	41:40	74 425	72,7%	CHF 118 751	Completed
C26-21	CVB-0388	Monoclonal antibodies – vials	Corvane (internal)	2	10R vial	42 000	8,0	90	18:00	26.02.26 13:37	22:00	9:18	8:00	28.02.26 04:56	39:18	41 785	83,1%	CHF 112 035	Completed
C26-22	NVL-204	Monoclonal antibodies – vials	Client C-014	2	2R vial	108 000	1,0	180	9:00	28.02.26 13:56	20:00	11:53	6:00	02.03.26 03:50	37:53	107 693	83,8%	CHF 108 006	Completed
C26-23	CVB-0217S	Prefilled syringes – RTU nests	Corvane (internal)	2	1 mL long syringe	87 000	1,0	200	15:00	02.03.26 18:50	28:00	8:51	7:00	04.03.26 14:41	43:51	86 711	81,5%	CHF 125 003	Completed
C26-24	ENZ-061	Enzymes and fusion proteins – vials	Client C-031	2	6R vial	54 000	5,0	110	21:00	05.03.26 11:41	26:00	10:19	8:00	07.03.26 08:01	44:19	53 381	78,4%	CHF 126 310	Completed
C26-25	CVB-0217	Monoclonal antibodies – vials	Corvane (internal)	3	6R vial	99 000	4,0	120	12:00	07.03.26 20:01	22:00	16:42	7:00	09.03.26 17:43	45:42	98 601	82,0%	CHF 130 270	Completed
C26-26	HPX-077	Prefilled syringes – RTU nests	Client C-009	2	2.25 mL syringe	72 000	2,0	160	18:00	10.03.26 11:43	24:00	9:09	7:00	12.03.26 03:53	40:09	71 796	81,6%	CHF 114 460	Completed
C26-27	NVL-204	Monoclonal antibodies – vials	Client C-014	2	2R vial	90 000	1,0	180	12:00	12.03.26 15:53	20:00	10:11	6:00	14.03.26 04:05	36:11	89 022	80,8%	CHF 103 164	Completed
C26-28	CVB-0388	Monoclonal antibodies – vials	Corvane (internal)	2	10R vial	45 000	8,0	90	15:00	14.03.26 19:05	22:00	11:21	8:00	16.03.26 12:26	41:21	44 977	73,3%	CHF 117 865	Completed
C26-29	CVB-0217S	Prefilled syringes – RTU nests	Corvane (internal)	2	1 mL long syringe	84 000	1,0	200	12:00	17.03.26 00:26	28:00	8:32	7:00	18.03.26 19:58	43:32	83 323	81,4%	CHF 124 075	Completed
C26-30	FPR-918	Enzymes and fusion proteins – vials	Client C-022	2	10R vial	45 000	6,0	95	18:00	19.03.26 13:58	26:00	9:09	8:00	21.03.26 09:08	43:09	44 503	85,3%	CHF 122 996	Completed
C26-31	CVB-0217	Monoclonal antibodies – vials	Corvane (internal)	3	6R vial	96 000	4,0	120	27:00	22.03.26 12:08	22:00	16:40	7:00	24.03.26 09:48	45:40			CHF 130 150	In progress
C26-32	ENZ-061	Enzymes and fusion proteins – vials	Client C-031	1	6R vial	33 000	5,0	110	15:00	25.03.26 00:48	26:00	6:15	8:00	26.03.26 17:03	40:15			CHF 114 713	Planned
Total Q1				75		2 605 000									1545:03	2 418 364	81,0%	CHF 4 403 395	34

Green values in the Filling column are actual filling windows reported by the MES; blue cells are planning inputs. Service value = campaign duration × blended CDMO line rate of CHF 2,850 per line hour. Planned campaigns use the planning factor of 80 % on the nominal line speed.

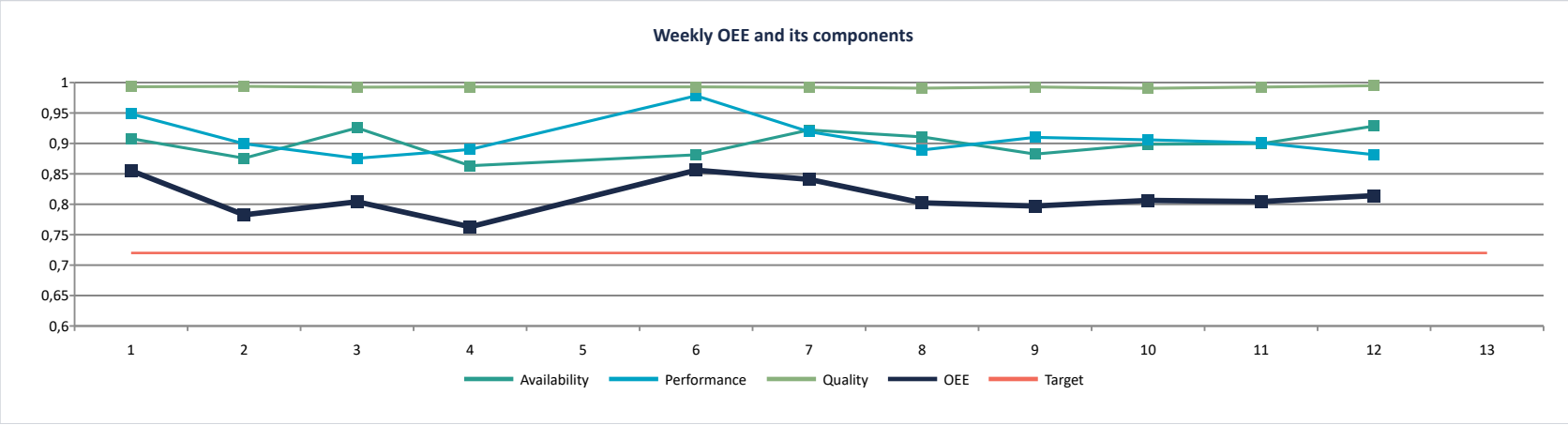
OEE by week — filling line FL-5

◄ Overview

Availability × performance × quality; planned production time from the campaign filling windows (array formulas), downtime from the MES event log, counts from the MES

Calendar				Time and counts						Performance indicators							
Week	From	To	Calendar (h)	Planned production (h)	Unplanned downtime (h)	Run time (h)	Ideal rate (/min)	Units processed	Good units	Availability	Performance	Quality	OEE	Target	Δ vs target	Utilisation	Trend
KW 01	29.12.25	04.01.26	168	36,0	3,3	32,7	136,8	254 530	252 766	90,8%	94,9%	99,3%	85,5%	72%	+13,5%	21%	
KW 02	05.01.26	11.01.26	168	26,1	3,3	22,9	178,8	220 846	219 460	87,6%	89,9%	99,4%	78,3%	72%	+6,3%	16%	
KW 03	12.01.26	18.01.26	168	39,8	3,0	36,8	105,6	204 380	202 827	92,5%	87,6%	99,2%	80,4%	72%	+8,4%	24%	
KW 04	19.01.26	25.01.26	168	33,2	4,5	28,6	172,9	264 421	262 534	86,3%	89,0%	99,3%	76,3%	72%	+4,3%	20%	
KW 05	26.01.26	01.02.26	168	0,0	0,0	0,0				#N/A	#N/A	#N/A	#N/A	72%	#N/A	0%	
KW 06	02.02.26	08.02.26	168	28,4	3,4	25,0	125,5	184 012	182 697	88,1%	97,8%	99,3%	85,6%	72%	+13,6%	17%	
KW 07	09.02.26	15.02.26	168	32,3	2,5	29,8	131,2	215 485	213 790	92,2%	91,9%	99,2%	84,1%	72%	+12,1%	19%	
KW 08	16.02.26	22.02.26	168	35,3	3,2	32,1	145,9	250 202	247 895	91,1%	88,9%	99,1%	80,2%	72%	+8,2%	21%	
KW 09	23.02.26	01.03.26	168	38,8	4,6	34,3	142,2	266 017	264 081	88,2%	91,0%	99,3%	79,7%	72%	+7,7%	23%	
KW 10	02.03.26	08.03.26	168	25,2	2,6	22,6	144,1	177 070	175 391	89,9%	90,6%	99,1%	80,6%	72%	+8,6%	15%	
KW 11	09.03.26	15.03.26	168	37,0	3,7	33,3	140,8	253 376	251 501	90,0%	90,1%	99,3%	80,4%	72%	+8,4%	22%	
KW 12	16.03.26	22.03.26	168	22,1	1,6	20,6	134,5	146 177	145 421	92,8%	88,2%	99,5%	81,4%	72%	+9,4%	13%	
KW 13	23.03.26	29.03.26	168	22,9	0,0	22,9	117,3			#N/A	#N/A	#N/A	#N/A	72%	#N/A	14%	
Q1			**2 184**	**354,2**	**35,5**	**318,7**	**140,3**	**2 436 516**	**2 418 363**	**90,0%**	**90,8%**	**99,3%**	**81,1%**	72%	**+9,1%**	**16,2%**	

Planned production time = sum of the overlaps of all commercial filling windows with the week (array formula over the Campaigns table). Ideal rate = overlap-weighted nominal speed. Performance = units processed ÷ (run time × 60 × ideal rate). Grey cells: no OEE (shutdown week 5, week 13 in progress). OEE target 72 % (site KPI 2026).



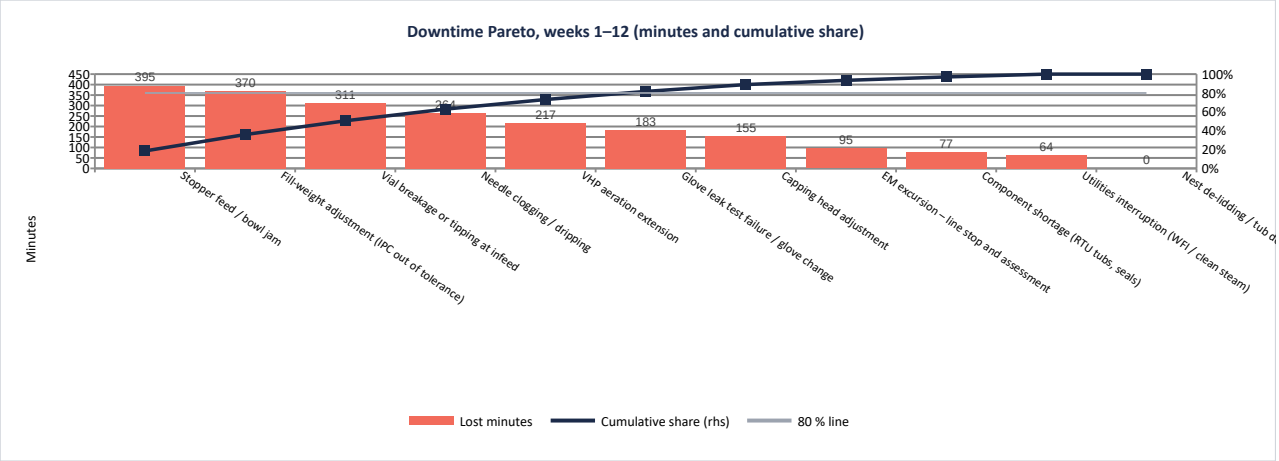
Unplanned downtime — Pareto analysis

◂ Overview

Stops during filling windows recorded in the MES, Q1 2026 (weeks 1–12); categories ranked by lost minutes with cumulative share

Pareto of downtime categories (sorted by formula: LARGE on a tie-broken key)

Rank	Category	Events	Minutes	Hours	Share	Typical root cause and countermeasure	
1	Stopper feed / bowl jam	16	395	6,6	18,5%	18,5%	Bowl vibration amplitude drifts with stopper lot; weekly amplitude check added to SOP FLS-OP-12.
2	Fill-weight adjustment (IPC out of tolerance)	15	370	6,2	17,4%	35,9%	Viscosity of high-concentration batches; pre-run weight check on 50 units before release.
3	Vial breakage or tipping at infeed	11	311	5,2	14,6%	50,5%	Infeed screw changeparts worn on 6R format; spare set ordered, replaced in shutdown week.
4	Needle clogging / dripping	10	264	4,4	12,4%	62,9%	Protein film at needle tip after long idle; needle purge sequence before restart.
5	VHP aeration extension	8	217	3,6	10,2%	73,1%	Aeration to < 1 ppm slower with full RTU load; load pattern optimised.
6	Glove leak test failure / glove change	6	183	3,1	8,6%	81,7%	Pin-holes found at glove ports 3 and 7; glove change interval reduced to 6 weeks.
7	Capping head adjustment	8	155	2,6	7,3%	88,9%	Crimp force drift on capping head 2; torque monitoring alarm narrowed.
8	EM excursion – line stop and assessment	1	95	1,6	4,5%	93,4%	Grade A particle count above action limit during intervention; line stopped, assessed, restarted.
9	Component shortage (RTU tubs, seals)	3	77	1,3	3,6%	97,0%	RTU tub delivery delayed by supplier; safety stock raised to 3 weeks.
10	Utilities interruption (WFI / clean steam)	1	64	1,1	3,0%	100,0%	Clean-steam pressure drop during header maintenance of a neighbouring line.
11	Nest de-lidding / tub de-bagging fault	0	0	0,0	0,0%	100,0%	Tyvek lid adhesion variation; de-lidding speed reduced for lot 24-117.
Total		**79**	**2 131**	**35,5**	**100%**		



Event log (Excel table, filterable)

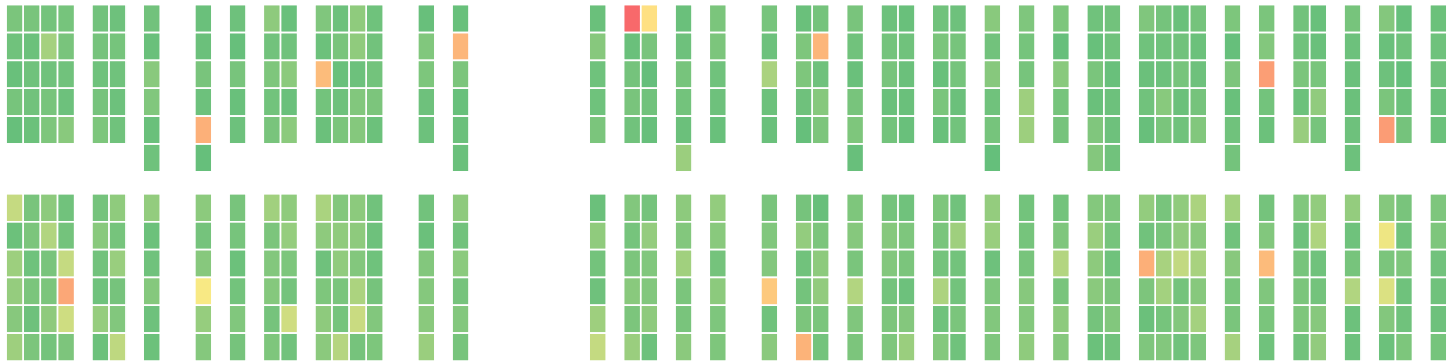
No.	Start	Week	Shift	Campaign	Product	Reason code	Reason	Minutes	Duration	Comment
1	mar 30.12. 18:52	KW 01	L	C26-01	CVB-0217	VHP	VHP aeration extension	37	0:37	
2	mar 30.12. 19:45	KW 01	L	C26-01	CVB-0217	NDL	Needle clogging / dripping	16	0:16	
3	mar 30.12. 20:35	KW 01	L	C26-01	CVB-0217	VBK	Vial breakage or tipping at infeed	10	0:10	
4	ven 02.01. 01:03	KW 01	N	C26-02	NVL-204	FWT	Fill-weight adjustment (IPC out of tolerance)	19	0:19	
5	ven 02.01. 02:42	KW 01	N	C26-02	NVL-204	FWT	Fill-weight adjustment (IPC out of tolerance)	54	0:54	
6	ven 02.01. 05:55	KW 01	N	C26-02	NVL-204	NDL	Needle clogging / dripping	8	0:08	
7	dim 04.01. 18:40	KW 01	L	C26-03	ENZ-061	FWT	Fill-weight adjustment (IPC out of tolerance)	23	0:23	
8	dim 04.01. 22:52	KW 01	N	C26-03	ENZ-061	NDL	Needle clogging / dripping	32	0:32	
9	mer 07.01. 03:15	KW 02	N	C26-04	CVB-0217S	STP	Stopper feed / bowl jam	57	0:57	
10	mer 07.01. 08:15	KW 02	E	C26-04	CVB-0217S	GLV	Glove leak test failure / glove change	19	0:19	Glove port 7 failed leak test; glo
11	mer 07.01. 11:39	KW 02	E	C26-04	CVB-0217S	FWT	Fill-weight adjustment (IPC out of tolerance)	25	0:25	
12	sam 10.01. 04:10	KW 02	N	C26-05	HPX-077	VBK	Vial breakage or tipping at infeed	56	0:56	
13	sam 10.01. 04:34	KW 02	N	C26-05	HPX-077	MAT	Component shortage (RTU tubs, seals)	38	0:38	Waiting for RTU tub lot release t
14	lun 12.01. 17:08	KW 03	L	C26-06	CVB-0388	STP	Stopper feed / bowl jam	13	0:13	
15	lun 12.01. 17:37	KW 03	L	C26-06	CVB-0388	VHP	VHP aeration extension	40	0:40	
16	mer 14.01. 18:38	KW 03	L	C26-07	CVB-0217	MAT	Component shortage (RTU tubs, seals)	24	0:24	Waiting for RTU tub lot release t
17	mer 14.01. 20:50	KW 03	L	C26-07	CVB-0217	STP	Stopper feed / bowl jam	23	0:23	
18	mer 14.01. 21:37	KW 03	L	C26-07	CVB-0217	CAP	Capping head adjustment	6	0:06	
19	mer 14.01. 23:02	KW 03	N	C26-07	CVB-0217	FWT	Fill-weight adjustment (IPC out of tolerance)	14	0:14	
20	sam 17.01. 23:54	KW 03	N	C26-08	FPR-918	GLV	Glove leak test failure / glove change	25	0:25	Glove port 3 failed leak test; glo
21	dim 18.01. 02:43	KW 03	N	C26-08	FPR-918	STP	Stopper feed / bowl jam	33	0:33	
22	mar 20.01. 03:14	KW 04	N	C26-09	NVL-204	UTL	Utilities interruption (WFI / clean steam)	64	1:04	Clean-steam header pressure < 2
23	mar 20.01. 03:53	KW 04	N	C26-09	NVL-204	VBK	Vial breakage or tipping at infeed	9	0:09	
24	mar 20.01. 12:15	KW 04	E	C26-09	NVL-204	STP	Stopper feed / bowl jam	20	0:20	
25	mar 20.01. 12:46	KW 04	E	C26-09	NVL-204	VBK	Vial breakage or tipping at infeed	33	0:33	
26	mar 20.01. 14:59	KW 04	L	C26-09	NVL-204	STP	Stopper feed / bowl jam	18	0:18	
27	ven 23.01. 02:33	KW 04	N	C26-10	ENZ-061	STP	Stopper feed / bowl jam	48	0:48	
28	dim 25.01. 14:20	KW 04	L	C26-11	CVB-0217S	FWT	Fill-weight adjustment (IPC out of tolerance)	28	0:28	
29	dim 25.01. 16:41	KW 04	L	C26-11	CVB-0217S	VBK	Vial breakage or tipping at infeed	52	0:52	
30	mer 04.02. 18:21	KW 06	L	C26-12	CVB-0388	EMX	EM excursion – line stop and assessment	95	1:35	Particle count 4,380/m³ ≥ 0.5 µm
31	mer 04.02. 18:37	KW 06	L	C26-12	CVB-0388	FWT	Fill-weight adjustment (IPC out of tolerance)	28	0:28	
32	mer 04.02. 21:33	KW 06	L	C26-12	CVB-0388	STP	Stopper feed / bowl jam	20	0:20	
33	mer 04.02. 21:41	KW 06	L	C26-12	CVB-0388	NDL	Needle clogging / dripping	6	0:06	
34	sam 07.02. 02:30	KW 06	N	C26-13	HPX-077	NDL	Needle clogging / dripping	21	0:21	
35	sam 07.02. 04:37	KW 06	N	C26-13	HPX-077	FWT	Fill-weight adjustment (IPC out of tolerance)	9	0:09	
36	sam 07.02. 08:22	KW 06	E	C26-13	HPX-077	FWT	Fill-weight adjustment (IPC out of tolerance)	23	0:23	
37	lun 09.02. 14:33	KW 07	L	C26-14	CVB-0217	VBK	Vial breakage or tipping at infeed	6	0:06	
38	lun 09.02. 17:03	KW 07	L	C26-14	CVB-0217	VBK	Vial breakage or tipping at infeed	30	0:30	
39	lun 09.02. 18:06	KW 07	L	C26-14	CVB-0217	STP	Stopper feed / bowl jam	6	0:06	
40	jeu 12.02. 10:44	KW 07	E	C26-15	NVL-204	VHP	VHP aeration extension	24	0:24	
41	jeu 12.02. 12:18	KW 07	E	C26-15	NVL-204	VHP	VHP aeration extension	20	0:20	
42	dim 15.02. 00:45	KW 07	N	C26-16	FPR-918	VBK	Vial breakage or tipping at infeed	41	0:41	
43	dim 15.02. 02:07	KW 07	N	C26-16	FPR-918	STP	Stopper feed / bowl jam	24	0:24	
44	mar 17.02. 04:32	KW 08	N	C26-17	CVB-0217S	VBK	Vial breakage or tipping at infeed	26	0:26	
45	mar 17.02. 09:00	KW 08	E	C26-17	CVB-0217S	CAP	Capping head adjustment	23	0:23	
46	mar 17.02. 11:04	KW 08	E	C26-17	CVB-0217S	VBK	Vial breakage or tipping at infeed	17	0:17	
47	jeu 19.02. 22:01	KW 08	N	C26-18	ENZ-061	STP	Stopper feed / bowl jam	14	0:14	
48	jeu 19.02. 22:49	KW 08	N	C26-18	ENZ-061	STP	Stopper feed / bowl jam	42	0:42	
49	ven 20.02. 02:31	KW 08	N	C26-18	ENZ-061	FWT	Fill-weight adjustment (IPC out of tolerance)	7	0:07	
50	dim 22.02. 14:23	KW 08	L	C26-19	CVB-0217	NDL	Needle clogging / dripping	17	0:17	
51	dim 22.02. 22:49	KW 08	N	C26-19	CVB-0217	VBK	Vial breakage or tipping at infeed	31	0:31	
52	dim 22.02. 23:21	KW 08	N	C26-19	CVB-0217	VHP	VHP aeration extension	12	0:12	
53	lun 23.02. 00:06	KW 09	N	C26-19	CVB-0217	NDL	Needle clogging / dripping	60	1:00	
54	mer 25.02. 09:23	KW 09	E	C26-20	HPX-077	GLV	Glove leak test failure / glove change	54	0:54	Glove port 5 failed leak test; glo
55	mer 25.02. 10:28	KW 09	E	C26-20	HPX-077	STP	Stopper feed / bowl jam	33	0:33	
56	ven 27.02. 16:03	KW 09	L	C26-21	CVB-0388	CAP	Capping head adjustment	17	0:17	
57	ven 27.02. 18:26	KW 09	L	C26-21	CVB-0388	GLV	Glove leak test failure / glove change	52	0:52	Glove port 7 failed leak test; glo
58	dim 01.03. 10:45	KW 09	E	C26-22	NVL-204	STP	Stopper feed / bowl jam	14	0:14	
59	dim 01.03. 19:56	KW 09	L	C26-22	NVL-204	FWT	Fill-weight adjustment (IPC out of tolerance)	28	0:28	
60	dim 01.03. 20:29	KW 09	L	C26-22	NVL-204	FWT	Fill-weight adjustment (IPC out of tolerance)	16	0:16	
61	mer 04.03. 00:21	KW 10	N	C26-23	CVB-0217S	CAP	Capping head adjustment	28	0:28	
62	mer 04.03. 04:11	KW 10	N	C26-23	CVB-0217S	STP	Stopper feed / bowl jam	24	0:24	
63	ven 06.03. 16:15	KW 10	L	C26-24	ENZ-061	NDL	Needle clogging / dripping	27	0:27	
64	ven 06.03. 16:58	KW 10	L	C26-24	ENZ-061	CAP	Capping head adjustment	35	0:35	
65	dim 08.03. 23:50	KW 10	N	C26-25	CVB-0217	FWT	Fill-weight adjustment (IPC out of tolerance)	39	0:39	
66	lun 09.03. 04:00	KW 11	N	C26-25	CVB-0217	CAP	Capping head adjustment	8	0:08	
67	lun 09.03. 04:15	KW 11	N	C26-25	CVB-0217	VHP	VHP aeration extension	7	0:07	
68	lun 09.03. 05:37	KW 11	N	C26-25	CVB-0217	STP	Stopper feed / bowl jam	6	0:06	
69	mer 11.03. 14:52	KW 11	L	C26-26	HPX-077	VHP	VHP aeration extension	36	0:36	
70	mer 11.03. 17:17	KW 11	L	C26-26	HPX-077	CAP	Capping head adjustment	17	0:17	
71	ven 13.03. 17:54	KW 11	L	C26-27	NVL-204	VHP	VHP aeration extension	41	0:41	
72	ven 13.03. 19:52	KW 11	L	C26-27	NVL-204	FWT	Fill-weight adjustment (IPC out of tolerance)	43	0:43	
73	dim 15.03. 17:52	KW 11	L	C26-28	CVB-0388	NDL	Needle clogging / dripping	50	0:50	
74	dim 15.03. 20:33	KW 11	L	C26-28	CVB-0388	GLV	Glove leak test failure / glove change	15	0:15	Glove port 2 failed leak test; glo
75	lun 16.03. 01:34	KW 12	N	C26-28	CVB-0388	MAT	Component shortage (RTU tubs, seals)	15	0:15	Waiting for RTU tub lot release t
76	mer 18.03. 08:45	KW 12	E	C26-29	CVB-0217S	FWT	Fill-weight adjustment (IPC out of tolerance)	14	0:14	
77	mer 18.03. 11:17	KW 12	E	C26-29	CVB-0217S	NDL	Needle clogging / dripping	27	0:27	
78	ven 20.03. 22:08	KW 12	N	C26-30	FPR-918	CAP	Capping head adjustment	21	0:21	
79	ven 20.03. 23:47	KW 12	N	C26-30	FPR-918	GLV	Glove leak test failure / glove change	18	0:18	Glove port 7 failed leak test; glo
Total								2131	35:31	

Environmental monitoring — Grade A and B, Q1 2026

Overview

Daily maximum of non-viable particles ≥ 0.5 µm per m³ (continuous monitoring during filling) and weekly viable counts; colour scales relative to alert and action limits

Point	Location	Grade	Alert /m³	Action /m³	Max
Grade A — isolator interior (in operation)					
A-01	Filling needles – active air	A	1,0E+03	3,52E+03	4 380
A-02	Stopper bowl and chute	A	1,0E+03	3,52E+03	2 032
A-03	Vial infeed turntable	A	1,0E+03	3,52E+03	2 488
A-04	Weighing station	A	1,0E+03	3,52E+03	375
A-05	Stoppering star wheel	A	1,0E+03	3,52E+03	2 523
A-06	Nest de-lidding (PFS)	A	1,0E+03	3,52E+03	357
Grade B — surrounding clean room (in operation)					
B-01	Material airlock MAL-2	B	1,0E+05	3,52E+05	62 834
B-02	RTU tub de-bagging station	B	1,0E+05	3,52E+05	89 291
B-03	Transfer hatch to isolator	B	1,0E+05	3,52E+05	216 347
B-04	Gowning room exit	B	1,0E+05	3,52E+05	231 335
B-05	Isolator glove-port side	B	1,0E+05	3,52E+05	69 052
B-06	Capping zone enclosure	B	1,0E+05	3,52E+05	208 294



Days with result ≥ alert limit (all points)						1		1		1		1		1	1		1	1	1

Viable monitoring — weekly totals (CFU); alert and action levels per EU GMP Annex 1

Code	Method	Grade	Alert	Action	Q1 total	KW 1	KW 2	KW 3	KW 4	KW 5	KW 6	KW 7	KW 8	KW 9	KW 10	KW 11	KW 12	KW 13
A-SP	Grade A settle plates (Ø 90 mm, 4 h)	A	1/2	≥ 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
A-CP	Grade A contact plates	A	1/2	≥ 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
A-AA	Grade A active air (1 m³)	A	1/2	≥ 1	1	0	0	0	0	0	1	0	0	0	0	0	0	0
A-GL	Glove prints (5 fingers)	A	1/2	≥ 1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
B-SP	Grade B settle plates (4 h)	B	3	≥ 5	17	1	2	3	1	1	0	3	0	1	0	2	3	0
B-CP	Grade B contact plates	B	3	≥ 5	15	0	3	2	2	1	1	0	0	1	3	1	1	0
B-AA	Grade B active air (1 m³)	B	6	≥ 10	25	2	2	2	1	0	2	4	0	3	4	4	0	1

Heat-map cells hide their values (custom number format ;;;) and are coloured by a 3-colour scale: green 0, yellow at the alert level, red at the action level of the grade. Blank grey cells: no filling on that day. Grade A alert of ½ CFU means that any growth is evaluated.

Shift roster FL-5 — weeks 6 to 9 (2 to 29 February 2026)

Four crews, three-shift system Monday to Friday; week 8 is the shutdown week with day shifts and training

Name	Role	Crew	FTE	February 2026																											Shifts	Nights	Hours	Target	Balance
				lun 02.02.	mar 03.02.	mer 04.02.	jeu 05.02.	ven 06.02.	sam 07.02.	dim 08.02.	lun 09.02.	mar 10.02.	mer 11.02.	jeu 12.02.	ven 13.02.	sam 14.02.	dim 15.02.	lun 16.02.	mar 17.02.	mer 18.02.	jeu 19.02.	ven 20.02.	sam 21.02.	dim 22.02.	lun 23.02.	mar 24.02.	mer 25.02.	jeu 26.02.	ven 27.02.	sam 28.02.	dim 01.03.					
Nadia Imesch	Shift lead	**A**	1	E	E	E	E	E	–	–	L	L	L	L	L	–	–	D	D	D	D	D	–	–	D	D	D	D	D	–	–	20	0	155,0	168,0	-13,0 h
Patrick Zurbriggen	Operator	**A**	1	E	E	E	E	E	–	–	L	L	L	U	U	–	–	D	D	D	D	D	–	–	D	D	D	D	D	–	–	18	0	140,0	151,2	-11,2 h
Laura Kalbermatten	Operator	**A**	1	E	E	E	E	E	–	–	L	L	L	L	L	–	–	D	D	D	D	D	–	–	D	D	D	D	D	–	–	20	0	155,0	168,0	-13,0 h
Jonas Werlen	Operator	**A**	4/5	E	E	E	E	–	E	–	L	L	L	L	–	–	–	D	D	D	D	–	–	–	D	D	D	D	–	–	–	17	0	131,5	134,4	-2,9 h
Mirjam Heinzmann	Operator	**A**	1	E	E	E	E	E	–	–	L	L	L	L	L	–	–	D	D	D	D	D	–	–	D	D	D	D	D	–	–	20	0	155,0	168,0	-13,0 h
Dario Bregy	Operator	**A**	1	E	E	E	E	E	–	–	L	L	L	L	L	–	–	D	D	D	D	D	–	–	D	D	D	T	D	–	–	20	0	154,8	168,0	-13,3 h
Fabian Supersaxo	Shift lead	**B**	1	L	L	L	L	L	–	–	N	N	N	N	N	–	–	D	D	D	D	D	–	–	E	E	E	E	E	–	–	20	5	152,5	168,0	-15,5 h
Selina Imboden	Operator	**B**	1	L	L	L	L	L	–	–	N	N	N	N	N	–	–	D	D	D	D	D	–	–	E	E	E	E	E	–	–	20	5	152,5	168,0	-15,5 h
Kevin Schnydrig	Operator	**B**	1	L	L	L	K	K	–	–	N	N	N	N	N	–	–	D	D	D	D	D	–	–	E	E	E	E	E	–	–	18	5	137,5	151,2	-13,7 h
Elena Ruppen	Operator	**B**	1/2	L	L	–	–	–	–	–	N	N	–	–	–	–	–	D	D	–	–	–	–	–	E	E	–	–	–	E	–	9	2	68,5	84,0	-15,5 h
Marco Lochmatter	Operator	**B**	1	L	L	L	L	L	–	–	N	N	N	N	N	–	–	D	D	D	D	D	–	–	E	E	E	E	E	–	–	20	5	152,5	168,0	-15,5 h
Yasmin Chanton	Operator	**B**	1	L	L	L	L	L	–	–	N	N	U	U	N	–	–	D	D	D	D	D	–	–	E	E	E	E	E	–	–	18	3	137,5	151,2	-13,7 h
Sandro Abgottspon	Shift lead	**C**	1	N	N	N	N	N	–	–	D	D	D	D	D	–	–	T	T	T	T	T	–	–	L	L	L	L	L	–	–	20	5	153,8	168,0	-14,3 h
Tanja Furrer	Operator	**C**	1	N	N	N	N	N	–	–	D	D	D	D	D	–	–	T	T	T	T	T	–	–	L	L	L	L	L	–	–	20	5	153,8	168,0	-14,3 h
Luca Venetz	Operator	**C**	1	N	N	N	N	N	–	–	D	D	D	D	D	–	–	T	T	T	T	T	–	–	L	U	U	U	U	–	–	16	5	123,8	134,4	-10,7 h
Ramona Summermatter	Operator	**C**	4/5	N	N	N	N	–	–	–	D	D	D	D	–	–	–	T	T	T	T	–	–	–	L	L	L	L	–	–	–	16	4	123,0	134,4	-11,4 h
Reto Andenmatten	Operator	**C**	1	N	N	N	N	N	–	–	D	D	D	D	D	–	–	T	T	T	T	T	–	–	L	L	L	L	L	–	–	20	5	153,8	168,0	-14,3 h
Ilaria Pfammatter	Operator	**C**	1	N	N	N	N	N	–	–	D	K	D	D	D	–	–	T	T	T	T	T	–	–	L	L	L	L	L	–	–	19	5	145,8	159,6	-13,9 h
Stefan Gsponer	Shift lead	**D**	1	D	D	D	D	D	–	–	E	E	E	E	E	–	–	T	T	T	T	T	–	–	N	N	N	N	N	–	–	20	5	153,8	168,0	-14,3 h
Martina Biner	Operator	**D**	1	D	D	D	D	D	–	–	E	E	E	E	E	–	–	T	T	T	T	T	–	–	N	N	N	N	N	–	–	20	5	153,8	168,0	-14,3 h
Noah Jossen	Operator	**D**	1	T	T	D	D	D	–	–	E	E	E	E	E	–	–	T	T	T	T	T	–	–	N	N	N	N	N	–	–	20	5	153,3	168,0	-14,8 h
Chiara Volken	Operator	**D**	1	D	D	D	D	D	–	–	E	E	E	E	E	E	–	T	T	T	T	T	–	–	N	N	N	N	N	–	–	21	5	161,3	168,0	-6,7 h
Pascal Truffer	Operator	**D**	4/5	D	D	D	D	–	–	–	E	E	E	E	–	–	–	T	U	U	U	–	–	–	N	N	N	N	–	–	–	13	4	99,8	109,2	-9,4 h
Vanessa Zenhäusern	Operator	**D**	1	D	D	D	D	D	–	–	E	E	E	E	E	–	–	T	T	T	T	T	–	–	N	N	N	N	N	–	–	20	5	153,8	168,0	-14,3 h

Staffing per shift

E – Early	6	6	6	6	5	1		6	6	6	6	5	1											6	6	5	5	5	1						
L – Late	6	6	5	4	4			6	6	6	5	4												6	5	5	5	4							
N – Night	6	6	6	6	5			6	6	4	4	5												6	6	6	6	5							
D – Day / maintenance	5	5	6	6	5			6	5	6	6	5			12	12	11	11	10					6	6	6	5	5							

Minimum crew for a production shift: 4 operators including one shift lead (named range MinCrew); red cells are below minimum on a working day.

Shift definitions

Code	Description	Start	End	Break	Paid	Hours
E	Early	06:00	14:00	0:30	**7:30**	7,50
L	Late	14:00	22:00	0:30	**7:30**	7,50
N	Night	22:00	06:00	0:30	**7:30**	7,50
D	Day / maintenance	07:30	16:30	1:00	**8:00**	8,00
T	Training	08:00	16:30	0:45	**7:45**	7,75
U	Vacation				0:00	0,00
K	Sick leave				0:00	0,00
–	Off				0:00	0,00

Average skill level by crew (radar chart on the Charts sheet)

Crew	Aseptic gowning	Isolator operation	VHP cycle	Fill-weight control	Visual inspection	Line clearance
Crew A	3,0	3,0	2,3	2,0	2,3	2,8
Crew B	3,2	3,2	2,5	2,7	2,0	2,2
Crew C	3,7	2,7	2,8	2,5	2,0	2,5
Crew D	3,5	3,7	2,2	2,0	2,2	2,0

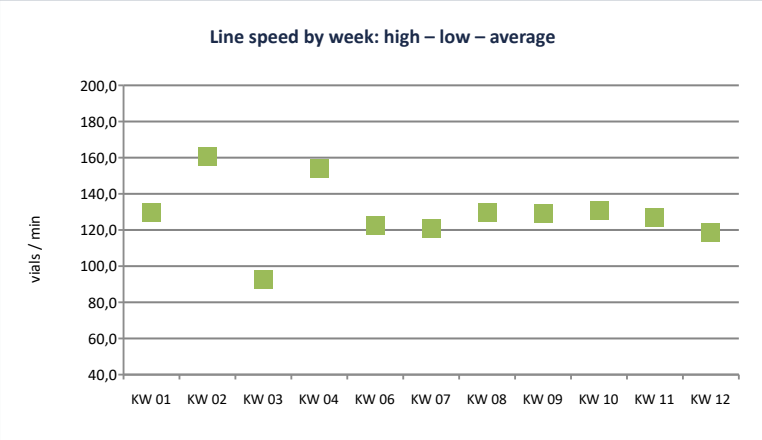
Skills matrix (0 = none, 4 = trainer)

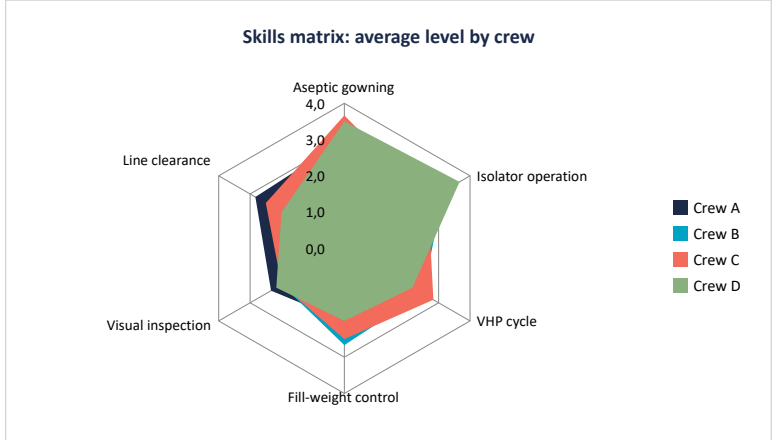
Name	Crew	Aseptic gowning	Isolator operation	VHP cycle	Fill-weight control	Visual inspection	Line clearance
Nadia Imesch	A	4	4	3	4	2	4
Patrick Zurbriggen	A	3	2	2	1	2	3
Laura Kalbermatten	A	3	4	3	1	3	2
Jonas Werlen	A	2	3	3	2	2	3
Mirjam Heinzmann	A	3	2	2	3	3	3
Dario Bregy	A	3	3	1	1	2	2
Fabian Supersaxo	B	4	4	3	3	3	4
Selina Imboden	B	3	3	2	3	2	1
Kevin Schnydrig	B	3	4	2	2	2	1
Elena Ruppen	B	3	3	3	3	1	3
Marco Lochmatter	B	3	2	2	2	2	3
Yasmin Chanton	B	3	3	3	3	2	1
Sandro Abgottspon	C	4	3	3	4	2	4
Tanja Furrer	C	4	3	3	3	1	3
Luca Venetz	C	2	3	3	2	1	2
Ramona Summermatter	C	4	3	3	2	3	2
Reto Andenmatten	C	4	2	3	2	2	1
Ilaria Pfammatter	C	4	2	2	2	3	3
Stefan Gsponer	D	4	4	3	3	4	2
Martina Biner	D	3	3	2	2	1	2
Noah Jossen	D	3	4	2	1	1	3
Chiara Volken	D	4	4	1	2	3	2
Pascal Truffer	D	3	4	3	2	1	1
Vanessa Zenhäusern	D	4	3	2	2	3	2

FL-5 performance charts

◂ Overview

Line speed range, crew skills, campaign efficiency and cumulative output · data tables below each pair of charts





Line speed by week (MES, vials per minute)

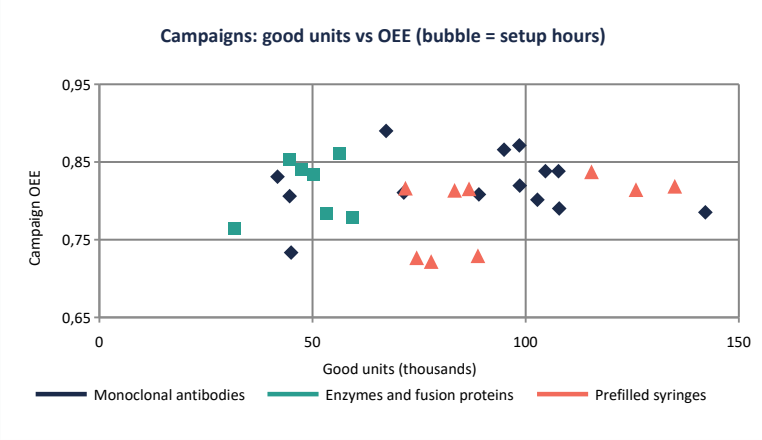
Week	High	Low	Average
KW 01	136,9	84,9	129,8
KW 02	181,9	107,9	160,8
KW 03	105,9	66,1	92,5
KW 04	171,4	105,8	153,9
KW 06	126,3	83,1	122,7
KW 07	129,7	75,4	120,6
KW 08	144,2	97,1	129,8
KW 09	143,5	75,0	129,4
KW 10	146,9	99,9	130,5
KW 11	141,9	88,8	126,9
KW 12	133,2	70,3	118,5

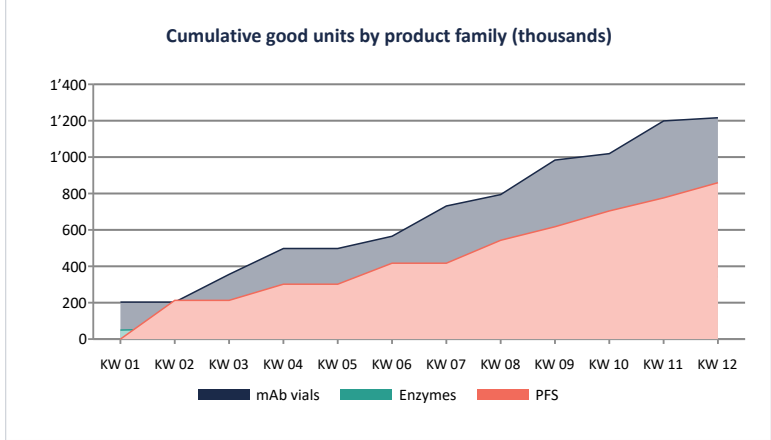
Average skill level by crew (from Shift roster)

Skill	Crew A	Crew B	Crew C	Crew D
Aseptic gowning	3,0	3,2	3,7	3,5
Isolator operatic	3,0	3,2	2,7	3,7
VHP cycle	2,3	2,5	2,8	2,2
Fill-weight contr	2,0	2,7	2,5	2,0
Visual inspectior	2,3	2,0	2,0	2,2
Line clearance	2,8	2,2	2,5	2,0

Cumulative good units by family (thousands)

Week	mAb vials	Enzymes	PFS	Total	Check
KW 01	203,1	49,6	0,0	**252,8**	✓
KW 02	203,1	56,3	212,8	**472,2**	✓
KW 03	355,6	106,6	212,8	**675,1**	✓
KW 04	497,8	138,2	301,6	**937,6**	✓
KW 05	497,8	138,2	301,6	**937,6**	✓
KW 06	565,0	138,2	417,0	**1120,3**	✓
KW 07	731,4	185,7	417,0	**1334,1**	✓
KW 08	793,9	245,1	542,9	**1582,0**	✓
KW 09	983,6	245,1	617,3	**1846,1**	✓
KW 10	1018,9	298,5	704,0	**2021,4**	✓
KW 11	1198,6	298,5	775,8	**2272,9**	✓
KW 12	1216,2	343,0	859,2	**2418,4**	✓





Campaign efficiency by product family (bubble data, linked to the Campaigns table)

Monoclonal antibodies

Campaign	Good (k)	OEE	Setup (h)
C26-01	98,5	87,1%	22
C26-02	104,6	83,8%	20
C26-06	44,6	80,6%	22
C26-07	107,9	79,0%	22
C26-09	142,1	78,5%	20
C26-12	67,3	89,0%	24
C26-14	71,4	81,1%	22
C26-15	94,9	86,6%	20
C26-19	102,7	80,1%	22
C26-21	41,8	83,1%	22
C26-22	107,7	83,8%	20
C26-25	98,6	82,0%	22
C26-27	89,0	80,8%	20
C26-28	45,0	73,3%	22

Enzymes and fusion proteins

Campaign	Good (k)	OEE	Setup (h)
C26-03	56,3	86,0%	26
C26-08	50,3	83,4%	26
C26-10	31,6	76,4%	26
C26-16	47,5	84,0%	26
C26-18	59,5	77,9%	26
C26-24	53,4	78,4%	26
C26-30	44,5	85,3%	26

Prefilled syringes

Campaign	Good (k)	OEE	Setup (h)
C26-04	135,0	81,9%	28
C26-05	77,8	72,2%	24
C26-11	88,8	72,9%	28
C26-13	115,4	83,7%	24
C26-17	125,9	81,4%	28
C26-20	74,4	72,7%	24
C26-23	86,7	81,5%	28
C26-26	71,8	81,6%	24
C26-29	83,3	81,4%	28

Notes, definitions and revision history

◄ Overview

Read together with the site procedure PP-0105 "Scheduling of aseptic filling lines"

Planning rules

Campaign chain	Each campaign starts after the previous campaign has ended plus a waiting time (drug substance thaw, component release, QA batch-record review). Changing one campaign shifts all later ones.
Filling time	Planned filling time = vials ÷ (nominal speed × planning factor 80 %). Completed campaigns show the actual filling window recorded by the MES.
Changeover	Setup includes line clearance, format change, VHP decontamination of the isolator (about 8 h) and set-up of the filling system; cleaning covers CIP/SIP of the product path.
Shutdown	The annual shutdown (week 5) is followed by the aseptic process simulation before commercial filling restarts.
Status date	The named range StatusDate (Overview) drives campaign status, the Gantt status marker and the staffing checks.

Definitions (OEE according to the site KPI handbook)

Availability	Run time ÷ planned production time; run time = planned production time − unplanned downtime.
Performance	Units processed ÷ (run time × ideal rate); ideal rate = nominal speed of the format.
Quality	Good units ÷ units processed (rejects from weight check, 100 % visual inspection excluded).
OEE	Availability × performance × quality.
Utilisation	Planned production time ÷ calendar time.

Abbreviations

APS	Aseptic process simulation (media fill)	**CFU**	Colony-forming unit
EM	Environmental monitoring	**IPC**	In-process control
KW	Calendar week (ISO 8601)	**MES**	Manufacturing execution system
PFS	Prefilled syringe	**RTU**	Ready-to-use (nested, pre-sterilised components)
VHP	Vaporised hydrogen peroxide		

Revision history

Version	Date	Author	Change
1.0	12.12.2025 16:20	F. Clausen	Quarterly plan issued (S&OP meeting 11.12.2025)
1.4	23.01.2026 11:05	F. Clausen	C26-10 reduced to one batch (drug substance shortage)
2.0	27.02.2026 09:30	D. Hischier	Re-plan after shutdown; three campaigns added in March
2.3	23.03.2026 07:45	D. Hischier	Status update week 13; OEE weeks 1–12 final