MENGM0056 - Product and Production Systems
Scenario 4: Medical Devices - Disposable Syringes

Hand-out for Group Coursework (2025/26)

UUID seed: 4e817fae-51df-4460-b08d-280698d95408 **Checksum:** 6159a6b56803

Purpose

This scenario addresses a regulated, high-volume medical-device operation. Your group receives seeded parameters for a syringe line and must deliver an improvement plan that achieves surge demand while maintaining compliance and quality, with limited scope for capital expenditure.

Narrative

A public health campaign has created a time-bound surge in orders for sterile syringes. The EO sterilisation chamber and downstream quarantine are known bottlenecks. Management prefers process and policy changes over new equipment in the short term. Regulatory compliance must be preserved.

Entities and flow (fixed structure)

Injection moulding (barrel, plunger) → Automated assembly with needle shield → 100% visual inspection → EO sterilisation (batch) → Quarantine (post-EO) → Clean-room packing → Release testing.

Baseline parameters (seeded)

Global

Shifts per day	3
Shift length	7.5 h
Demand (nominal)	122988 units/day
Surge magnitude	52% above nominal
On-time target	95%

Stations and process timings

Stage	Count	Time	Quality	Notes
Injection moulding	5	19.9 s/part	FPY 0.9969 (scrap 0.0086)	Multi-cavity average
Automated assembly	3	0.64 s/part	FPY 0.9858	Rework 76.0 s (success 0.83)
Visual inspection	1	0.6 s/part	Detect 0.98 (false fail 0.0041)	100% coverage
EO sterilisation (batch)	1	273.4 min/batch	-	Batch size 41802 units
Clean-room packing	9	-	FPY 0.9979	Operators; per-operator rate see policy

Buffer policy and quarantine

Max pre-EO buffer	5.6 h
Post-EO quarantine	22.4 h

Reliability

Resource	MTBF (min)	MTTR (min)
Moulding	571.7	28.8
Assembly	431.5	12.2
Inspection	681.8	15.0
EO	1108.7	45.2
Packing	731.5	10.1

Costs

Scrap cost	£0.15 /unit
Pack material cost	£0.06 /unit
EO sterilisation cost	£127.07 /batch
Labour cost	£17.03 /h
Rework labour cost	£19.85 /h
Quality escapes proxy	£11369 /million units

Required KPIs

- End-to-end lead time and on-time delivery probability under surge conditions.
- EO chamber utilisation, number of batches/day, and queue time into EO.
- Quarantine inventory and release rate; packing throughput and operator utilisation.
- FPY by stage and rolled throughput yield (RTY); rework rate and rework hours/day.
- Scrap cost per unit and expected cost of quality escapes.

Techniques to apply

- **Modelling & KPIs**: RTY ladder; EO batch sizing logic; capacity calculations.
- **Mathematical programming**: EO batch sequencing; shift and packing-station staffing to achieve surge output.
- **Uncertainty modelling**: Breakdown and false-fail distributions; demand surge profiles; contamination risk as rare events.
- **Simulation**: Discrete-event simulation focused on EO bottleneck, quarantine, and packing; test push vs. pull policies.
- **Metaheuristic optimisation**: Multi-objective tuning of batch sizes, start times, and buffer limits for on-time delivery vs. WIP.
- **CAE (optional)**: If proposing design or fixture changes affecting assembly time or defect modes.

Improvement levers (examples, not exhaustive)

- EO campaign scheduling (stagger starts, night runs) within pre-defined safety windows.
- Rework triage rules after visual inspection to minimise non-value-adding loops.
- Temporary reallocation of operators to packing during surge hours; dynamic takt alignment.
- Adjust max pre-EO buffer and quarantine durations where compliant, evaluating risk and service impact.

Deliverables

1. A report (max 20 sides of A4 including figures and references; appendices unmarked but admissible as evidence).

2. The report should contain a surge-response plan demonstrating capacity to meet demand spike while maintaining compliance.
3. Model files (simulation, optimisation) as appendices or evidence.

Assessment emphasis

Appropriate KPI selection; correctness and transparency of models; evidence-based policy choices; robustness under uncertainty; and clear recommendations that respect regulatory constraints.

Data ethics and reproducibility

Report your UUID seed and any random seeds used within tools. Provide sufficient detail for independent regeneration of your parameter tables.