

OEM and Contract Manufacturing Capabilities

from SAFC Supply Solutions®



SAFC Supply Solutions® is the diagnostic manufacturer's single-stop OEM/contract manufacturing alternative to plant expansion or new market entry without capital outlay. Our OEM manufacturing services are supported by two US based facilities. The Ewing facility, located in St. Louis, Missouri, is the site utilized for general IVD manufacturing, such as clinical chemistry and molecular diagnostics. The Cherokee facility, also located in St. Louis, is the manufacturing site for the SAFC hematology and histology reagents.

Both facilities are FDA licensed and ISO 13485 certified. Key capabilities include:



Stain and dye solution manufacturing and automated filling

- Batch sizes from 100 L to 12,000 L
- Package sizes from 100 mL to 200 L

Flammable solvent formulations and automated filling

- Batch sizes from 100 L to 12,000 L
- Package sizes from 100 mL to 200 L
- OSHA process safety management compliant

Dry powder compounding

- Grinding/blending up to 200 kg
- 5% humidity suites (2)

Liquid compounding

- Blending up to 6,000 L
- 2,000 L jacketed tank with temperature range 2 – 50° C

Automated dry powder packaging

(humidity controlled below 5%)

- Line 1: 150 mg and up; 60 bottles/min
- Pouching: 5 to 200 g; 30 – 60 pouches/min

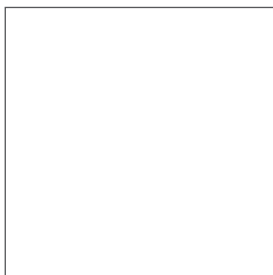
Automated liquid packaging

Line 1	5-1000 mL	55 bottles/min
Line 2	250-20,000 mL	24 bottles/min
Aseptic fill	0.25 mL to 1 L	120 bottles/min
Environmentally (HEPA filtered)	0.1 to 2 mL	40 bottles/min
Tube filler (min. batch size 25)	25µL to 2 mL	50 tubes/min
Cozzolli filler for lyophilization	1 to 30 mL	136–400 bottles/min
Vial filling line with Ivek filler	0.045 to 1.5 mL	140 vials/min

SAFC Supply Solutions™
Inspiring Science

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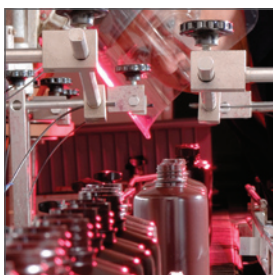
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Automated multiwell plate

manufacturing (Examples: Antibody, high-capacity capture plates, coating for cell culture application)

- Environmentally controlled manufacturing suite ISO Class 7 (10k)
- Oyster bay fillers (2): 96 well, 96 stripwell and 384 well; 1,000 plates/hr
- UV curing tunnel
- HIX drying oven: up to 150 °F; 4'x3'4"x6' (~80 sq ft)
- Saxon 5 Medical Bag Sealer
- Vacuum bag sealer for plates and configurable packaging options



Lyophilizers

- Multiple units up to 350 sq ft. shelf space
- One lot capacity of 80,000 five mL bottles
- Automated capper and labeling (dry powder line 1 or liquid line 1 or 2)

Drying

- Stokes vacuum drying tanks
- 20,000 x 20 cc vials/tank

Antibiotic packaging room

- Designed for safe handling of antibiotics
- Fill range 50 mg and up

Kit packaging

- Kit design: box, insert, and component layout
- Manual assembly: 2 to >20 components/kit

Labeling

- On site printing capabilities
- Experience with CE Mark process
- Private labeling

Life Science production

- Antibody purification, conjugation and labeling (i.e. agarose, HRP, AP, Fluorophores)
- Protein purification
 - 2 AKTA Automated chromatography workstations
 - 1 HPLC
 - Natural source, recombinant and fusion tagged (e.g. FLAG)
- 16 L fermentation
- Electrophoresis reagents
- Molecular biology reagents for:
 - Nucleic acid extraction and purification
 - qPCR and PCR reagents
- Custom formulations (such as ready mixes for PCR)

Quality systems and licenses

- cGMP 21CFR 820
- ISO 13485:2003
- CE marking (EU IVDD)
- 510(k) submissions
- DEA License

Life Science analytical testing for Biotech and Molecular Diagnostics

- Molecular testing such as: qPCR, PCR, western, northern, southern, spectrophotometry, gel electrophoresis, and nuclease contamination
- Molecular and proteomic kit suitability testing such as plasmid purification, cloning and protein depletion
- Immunological assays such as: agglutination, ELISA's, immunoelectrophoresis, ODD's, column chromatography
- Bioanalyzer is agilent's highly successful microfluidics-based platform for the analysis of DNA, RNA, proteins and cells

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