Saint Petersburg Scientific Research Institute of Vaccines and Sera of the FMBA of Russia

SPbSRIVS

Full-cycle developer and manufacturer of vaccines

The production meets Russian and international quality standards

First supplier of influenza vaccines to Latin America

Priority areas in development:

- Vaccines
- Biotechnological products

Research and Development Center

- Full-cycle of pharmaceutical product development
- Development and validation of analytical methods
- Support for transfer projects

Production

- Immunobiological Production Complex
- Recombinant Products Area
- Finished Dosage Forms Area
- Formulation Department

Quality Control

- Physico-chemical methods of analysis
- In vitro tests
- In vivo tests
- Microbiological tests

Warehouse Complex

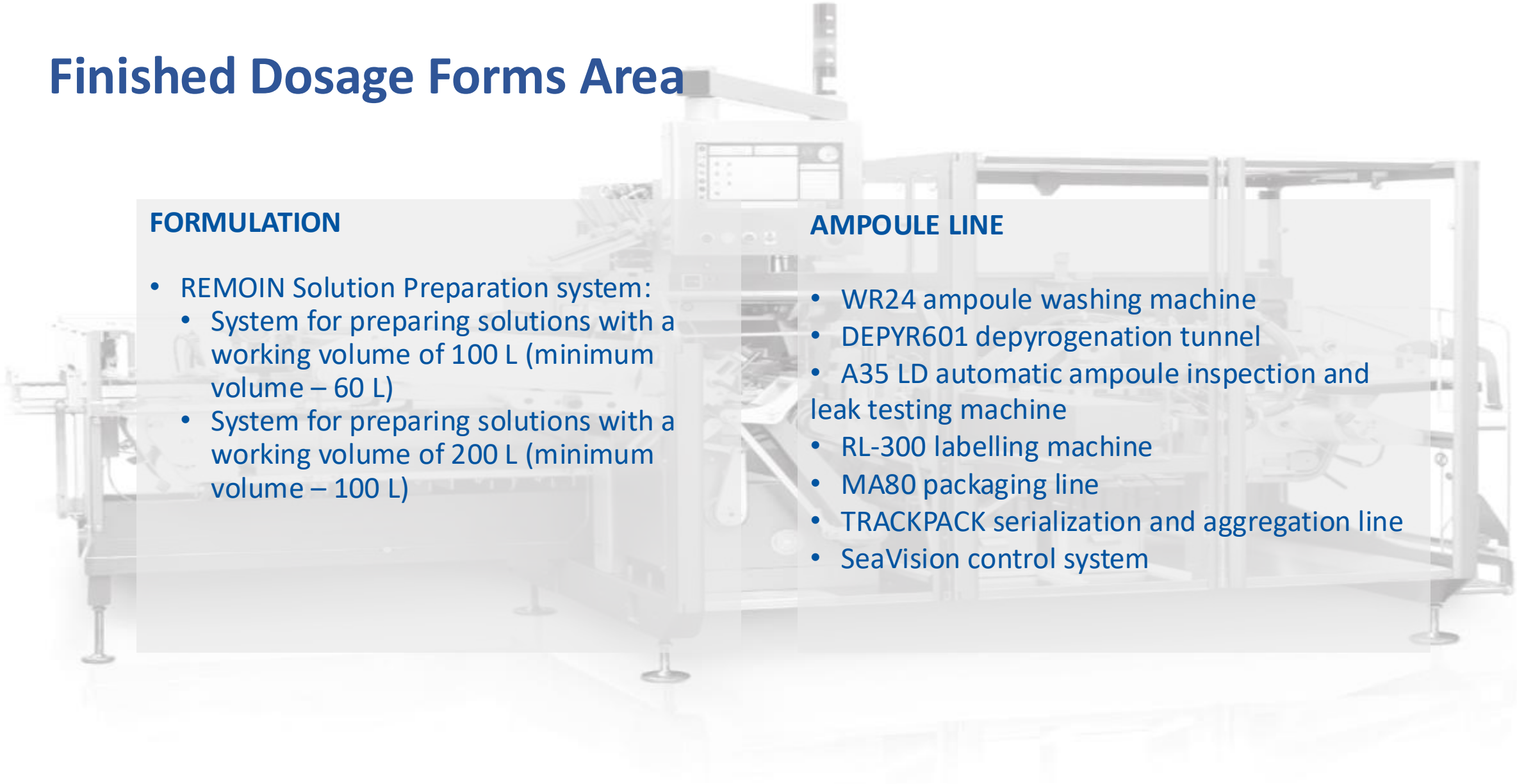
- Finished Products Warehouse with the ability to maintain a temperature of +4-8°C, with a total area of 256 m^2;
- Material Warehouse, 99 m^2;
- Glassware Warehouse, 154.6 m^2;
- Printed Products Warehouse, 150 m^2;

All premises of the warehouse complex have isolated areas for quarantine, defects, returned, recalled and released products

Cold chain logistics

- Experience in organizing and validating cold chain transatlantic transportation of thermolabile products

Finished Dosage Forms Area



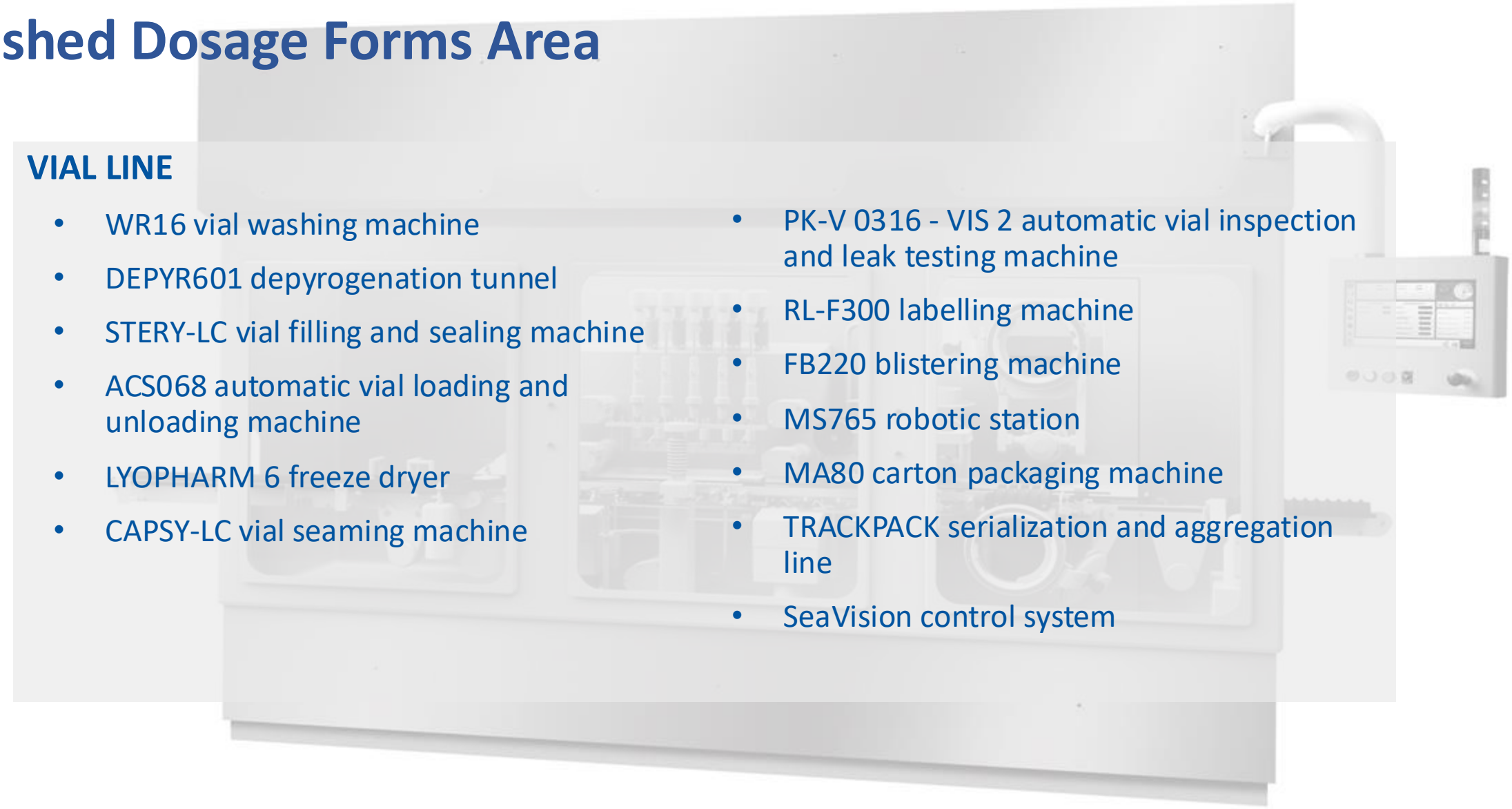
FORMULATION

- REMOIN Solution Preparation system:
  - System for preparing solutions with a working volume of 100 L (minimum volume – 60 L)
  - System for preparing solutions with a working volume of 200 L (minimum volume – 100 L)

AMPOULE LINE

- WR24 ampoule washing machine
- DEPYR601 depyrogenation tunnel
- A35 LD automatic ampoule inspection and leak testing machine
- RL-300 labelling machine
- MA80 packaging line
- TRACKPACK serialization and aggregation line
- SeaVision control system

Finished Dosage Forms Area



VIAL LINE

- WR16 vial washing machine
- DEPYR601 depyrogenation tunnel
- STERY-LC vial filling and sealing machine
- ACS068 automatic vial loading and unloading machine
- LYOPHARM 6 freeze dryer
- CAPSY-LC vial seaming machine
- PK-V 0316 - VIS 2 automatic vial inspection and leak testing machine
- RL-F300 labelling machine
- FB220 blistering machine
- MS765 robotic station
- MA80 carton packaging machine
- TRACKPACK serialization and aggregation line
- SeaVision control system

Production line formats

VIAL LINE

2R vials: Ø16, H35
10 vials per blister → pack No. 10

4R vials: Ø16, H45
10 vials per blister → pack No. 10

6R vials: Ø22, H40
10 vials per blister → pack No. 10

8R vials: Ø22, H45
10 vials per blister → pack No. 10

AMPOULE LINE

1 mL ampoules: Ø10.75, H67

10 ampoules per lodgment → pack No. 10

1 ampoule per lodgment → pack No. 1

Possibilities for retrofitting filling lines

In the vial line, the use of additional formats is possible:

- 10R
- 15R
- 20R
- 25R
- 30R

In the ampoule line, the use of additional formats is possible:

- 2 mL x 10.75
- 3 mL x 12.75
- 5 mL x 14.75
- 10 mL x 17.75
- 20 mL x 22.5
- 25 mL x 22.5
- 30 mL x 22.5

Performance

Equipment	2R max, v/h	2R operating, v/h	4R max, v/h	4R operating, v/h	6R max, v/h	6R operating, v/h	8R max, v/h	8R operating, v/h	Ampoules max	Ampoules operating
Washing machine and depyrogenation tunnel	11,000	165	10,000	150	9,000	135	8,000	120	24,000	360
Filling machine	11,000	165	10,000	150	9,000	135	8,000	120	24,000	360
Vial loading/unloading station	11,000	165	10,000	150	9,000	135	8,000	120	n/a	n/a
Sealing machine	11,000	165	10,000	150	9,000	135	8,000	120	n/a	n/a
Visual inspection and leak testing machine	11,000	165	10,000	150	9,000	135	8,000	120	18,000	270
Labelling machine	11,000	165	10,000	150	9,000	135	8,000	120	18,000	270
Blistering machine	11,000	165	10,000	150	9,000	135	8,000	120		
Carton packaging machine No. 10	11,000	165	10,000	150	9,000	135	8,000	120	24,000	400
TRACKPACK No. 10	11,000	165	10,000	150	9,000	135	8,000	120	36,000	600
Carton packaging machine No. 1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	3,000	50
TRACKPACK No. 1	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	3,600	60
TOTAL LINE SPEED	11,000	165	10,000	150	9,000	135	8,000	120	21,600	360
									16,200	270
									3,600	60

Pharmaceutical products in ampoules
(filling and secondary packaging)

Continuous batch production

- **Batch production time** 22 h. (including secondary packaging)
- **Max. solution volume** 200 L
- **Max. batch size** 350,000 amp.
- **Working days per year** 280 w.d.
- **Line capacity** up to 80,000,000 ampoules per year

One-shift batch production

- **Batch production time** 11 h. (including secondary packaging)
- **Min. solution volume** 100 L
- **Max. batch size** 175,000 amp.
- **Working days per year** 280 w.d.
- **Line capacity** up to 45,000,000 ampoules/year

Pharmaceutical products in vials
(filling and secondary packaging)

Operation pattern continuous production

2R/4R

- **Max. solution volume** 100 L*
- **Max. batch size** 166,000 vials
- **Working days per year** 280 w.d.
- **Line capacity** up to 40,000,000 vials per year

6R/8R

- **Max. solution volume** 200 L**
- **Max. batch size** 32,000 vials
- **Useful production days** 280 w.d.
- **Line capacity** up to 8,000,000 vials per year

**min. size - 60 L; ** min. size - 100 L;*

Operation pattern production of lyophilized products

2R/4R

- **Max. chamber load** 28,000 vials
- **Lyophilization cycle** 72 h.
- **Batches per month** 5
- **Max. number of batches per year** 60
- **Line capacity** 1,500,000 vials per year

6R/8R

- **Max. chamber load** 14,820 vials
- **Lyophilization cycle** 72 h.
- **Batches per month** 5
- **Max. number of batches per year** 60
- **Line capacity** 850,000 vials per year

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