

JSC "Grindeks" Quality Control Laboratory

FACT SHEET

- On 5 June 2014, JSC "Grindeks" ceremonially opened its renovated Quality Control Laboratory, one of the most advanced laboratories in the Baltics, compliant with world-class standards. The project was implemented in order to increase the productivity of the Quality Control Laboratory's microbiological and other analyses.
- Expansion and modernisation of the Quality Control Laboratory has been one of the most ambitious investment projects in quality area for JSC "Grindeks".
- Total project investments constituted 2.4 million euros, with 2.03 million euros invested in construction and 0.4 million euros in laboratory equipment and technical supply. The project was financed by the company's funds.
- The project of construction of the laboratory and installation of equipment took 2.5 years, and all reconstruction works were executed in 3 stages.
- Quality Control is provided in accordance with the requirements of the Good Manufacturing Practices and ISO 9001, ISO 17025 and ISO 14001 standards, generally guaranteeing safety and quality of the manufactured medicines.
- To have the project progress according to schedule, 62 meetings with construction contractors were held. The highest number of construction workers carrying out the construction works was 23.
- The project was developed and construction works were undertaken by general contractor SIA "RBSSKALS Būvradība". Works were performed by partners in Latvia and abroad: SIA "SC Celtnieks" (general construction works), SIA "Biant" (ventilation, air conditioning), SIA "RCBS" (heating, water supply, sewerage), SIA "NCS LV" (electricity, weak current), SIA "Lafivents" (automatic control systems), "CM Systems"/ Poland (treated water system design and construction), "Clean-tek Reinraumtechnik GmbH+Co.KG"/ Germany (design and construction supervision for cleanrooms). Architect Andra Bula was contracted for interior design.
- Total area of the quality Control laboratory is 1670 m² (755 m² of which were renovated). The total area of cleanrooms is 95m². 5 boxes for clean works and 2 boxes for work with contaminated materials have been assembled.
- The most innovative equipment: isolator with quick sterilisation, plate filling machine, which is capable of filling contact plates and 90 mm plates (productivity of the machine is about 530 plates/h – this used to be a manual process).
- The lab features a highly advanced automated control system for controlling the indoor microclimate, operation of utility systems and other processes, which will yield considerable energy savings. State of the art equipment will ensure that lab analyses are conducted in a convenient, safe, efficient and environmentally friendly manner: sterility

test isolator Bioquell Qube M-9 (manufacturer: "Bioquell UK Ltd.", England), contact plate filling machine IQ-C400 (manufacturer: "IQDesigns Inc.", USA), etc.

- The Quality Control Laboratory employs a staff of 64, including 10 qualified, experienced microbiologists who conduct microbiological analyses. Due to emphasising automation, the number of staff at the Quality Control Laboratory will not be increased.
- Prior to the reconstruction, in 2013, 7500 microbiological analyses were performed; after reconstruction, the number of analyses is planned to increase by 10%.
- JSC "Grindeks" will also provide analytical services to other companies in Latvia and abroad – required analyses of tablets, capsules, salves, gels, syrups, injections, active pharmaceutical ingredients, as well as validation of technology and cleaning, serial control and release of pharmaceutical products to EU and CIS markets.

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