SCINAI BIOSERVICES

Boutique end-to-end CDMO

Serving early stage biotech companies

cGMP Manufacturing

Manufacturing suites include clean rooms for:

- Upstream **fermentation**
- Downstream **purification**
- Media and buffer prep
- Vials and PFS automatic **aseptic filling**
- Labeling and visual inspection
- **Liposomal** drug formulation and production
- Facility meets **EMA and FDA GMP** standards
- Passed European QP (EMA) and Israeli MoH audits for Phase 3 clinical trial product

State-of-the-art Laboratories

Technical R&D and QC labs support:

- **Process development, optimization** and **scale-up**
- **Analytical methods** development
- In process controls and product release testing

Vast Pharma Experience

In-house expertise includes:

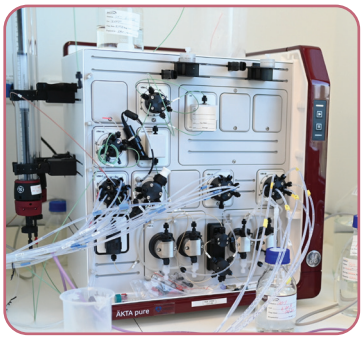
- 20 years of recombinant protein process development and cGMP manufacturing from preclinical through Phase 3 clinical trials
- Startup and big pharma leadership in USA, Israel, Europe, China, and Singapore
- Unique bacterial, yeast liposomal products, and VHH antibody (nanobody®) development and manufacturing

Biological drug development and manufacturing

Decades of accumulated experience in manufacturing process development, analytical method development, and quality control under GLP conditions coupled with robust QMS
~ Quality in all that we do ~

Scinai Immunotherapeutics Ltd. (Nasdaq: SCNI) is a biopharmaceutical company with two complementary business units, one focused on in-house development of innovative therapies, and the other a boutique end-to-end CDMO providing biological drug development, analytical methods development, clinical GMP manufacturing, and pre-clinical and clinical trial design and execution services to early stage biotech companies.

Our services include: Clone selection, host cell transformation, manufacturing process development and optimization, analytical methods development, cGMP manufacturing, aseptic fill & finish, QC testing, and storage controlled environment.



SCINAI.COM/CDMO

Proven track record

> **Extensive experience** in manufacturing process development, analytical method development, and quality control under GLP conditions coupled with robust QMS

> **Big pharma leadership** & **startup success** in USA, Israel, Europe, China, and Singapore

VHH Antibody Development and Pichia Production from Scratch

- Developed, optimized, purified, and upscaled VHH antibodies for manufacturing in our 300L fermentor using a Pichia pastoris expression system, with product used in a successful preclinical in vivo proof-of-concept study

Scale-up, Production, cGMP Aseptic filling for Phase 3 Clinical Trial

- Successful in-house development of recombinant protein vaccine candidate
- Drug substance scale-up and tech transfer to Scinai
- European QP and Israel MoH previously approved facility for Phase 3 cGMP fill & finish cGMP fill & finish of PFS for 12,400 participant Phase 3 trial

Top Tier Leadership

Amir Reichman, MSc, MBA
CEO
Global pharmaceutical engineering & supply chain leadership at GSK & Novartis

Dr. Tamar Ben-Yedidia, PhD
CSO
Co-invented & guided recombinant protein vaccine candidate from bench through Phase 3 trial

Elad Mark, BSc (Eng), MBA
COO
Led scale-up, tech transfer, manufacturing of recombinant proteins in China, mAbs for Novartis Singapore

Dr. Dalit Weinstein Fischer, PhD
CTO
Biological processes, specializing in improving fermentation processes

cGMP Production

cGMP Manufacturing Facility Suites

- Clean rooms for upstream, downstream, buffer and media preparation, and aseptic filling
- Sterile grade B clean room with separate access
- Designed to meet FDA and EMA cGMP manufacturing standards
- Fully segregated air system for each room
- Fully equipped suites including 30L and single-use 300L fermentors, continuous centrifuge, AKTA process, columns, single use mixers, and powder transfer systems
- Cleaning and sterilization suite with cGMP dish washer and autoclave; WFI, OFA, gases and CIP
- Automation: Building Management system 21 CFR Part 11 & GAMP 5

Deep In-house Pharma Experience

Dr. Tehila Sonnenfeld, PhD
Director of Production
Extensive experience in aseptic production under GMP conditions

- Decades of recombinant protein process development from bench through Phase 3
- cGMP manufacturing from preclinical through Phase 3 clinical trial

Upstream Process Development and Scale-up

Fermentation Process Development

Lab-scale process development and optimization under design of experiments (DoE) methodology incorporating Quality by Design principles, with high end equipment:

- Ambr® 250 system with four individual fermentor modules enables process characterization to simplify operations while increasing productivity

- 2L, 5L Biostat® B-DCU enables process development and optimization
- 30L stainless steel bioreactor ideal for scaling-up from pilot to production
- Fermentation of bacteria, yeast, fungi

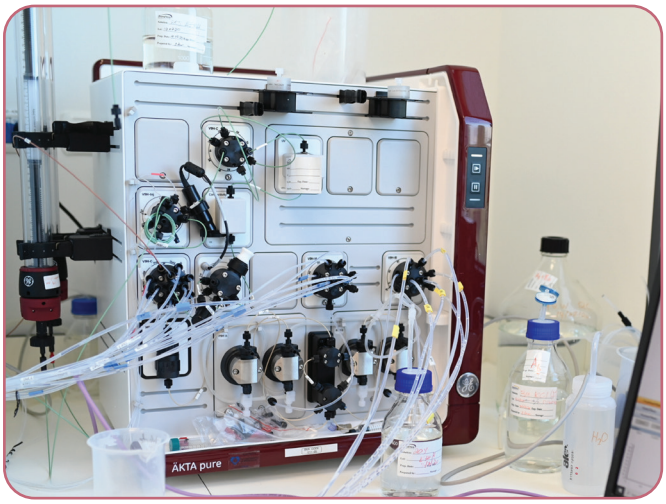
Deep In-house Process Development and Scale-up Experience

Zohar Gadri, MSc
Technical R&D Upstream Process Team Leader
Processes development and optimization; Protein purification from laboratory to GMP conditions

Downstream Process Development and Scale-up

Technical R&D Labs

Process development and optimization under design of experiments (DOE) methodology incorporating Quality by Design principles.



- From lab-scale development to optimized downstream production process
- Process development always with an eye towards commercial-scale production
- A variety of resins for screening, enabling process characterization, optimization, efficiency, and purity.
- Filtration and UFDF solutions – Wide range of HF, Dead-end, and cassettes
- ÄKTA readyflux™, ÄKTA pure™ 150, ÄKTA pilot, and ÄKTA process™, Sartoflow® Smart TFF System, for countless optional purification procedures
- Extensive range of columns up to 50L

Barry Cohen, MSc
Technical R&D Downstream Process Team Leader
Processes development and protein purification from laboratory to GMP standard conditions.

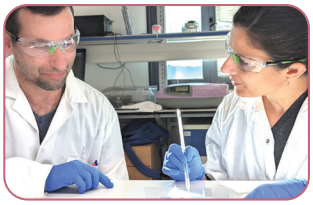
Navah Figov, MSc
Technical R&D Downstream Process Team Leader
Expert in process development and scale-up processes for GMP pharmaceutical manufacturing.

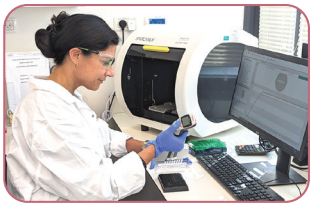
Analytical Method Development and Quality Control

Scinai CDMO's experienced team of scientists and state-of-the-art facility ensures accuracy and reliable analytical characterization, quality control and quality assurance services. Our boutique service includes custom packages for protein characterization to support regulatory applications.

Laboratory Analytical Capabilities

- Physicochemical methods for identity, purity, and heterogeneity (HPLC -PDA/FD, CE-SDS/cIEF, SDS-PAGE, Western Blot)
- Immunochemical assays using BLI technology for in-vitro potency and binding affinity (OCTET R8)
- Endotoxins determination by chromogenic kinetic assay (USP <85> & Ph. Eur. 2.6.14)
- Spectrophotometry for Total Protein Content (Ph. Eur. 2.5.33, Method 2, USP <507> Method IV)
- Product and process related impurities (SEC-HPLC, RP-HPLC, CE-SDS /cIEF)
- Particles size analysis (Spectral LUMiSizer)
- Host cell protein impurities (ELISA)
- Bioburden by membrane filtration (USP <61>)
- Stability studies (ICH Guideline Q1A (R2) and Q5C)





Dr. Oded Ovadia, PhD
Director of Analytical Methods & Preclinical Trials
Experienced in analytical development of biosimilar and innovative biomolecules

Merav Kamensky, MSc
Head of Quality Control
Biopharma QC and biological analytical method qualification experience

Quality in all that we do

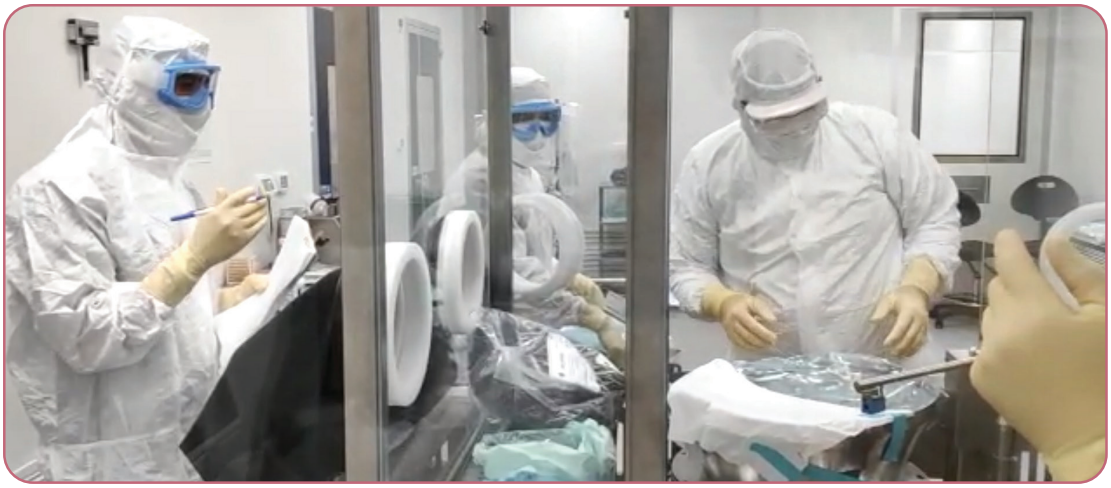
- Quality at every stage of a product's life cycle including safety assessment, clinical development, and manufacturing
- Ready to use Quality Management System (QMS): Dot compliance, Document Management System (DMS), Learning Management System (LMS)
- European QP and Israel MoH previously approved facility for Phase 3 cGMP fill & finish

Alona Tal, MSc
& Dr. Naama Adi Hen, PhD
Quality Assurance Sr. Managers

Aseptic Filling

Grade A Filling Machine

- Aseptic, automated filling machine under Grade A (RABS) located in a Grade B background
- Designed to meet FDA and EMA cGMP manufacturing standards
- Suitable for various types and volumes of syringes and vials
- Fully equipped supporting suites
- Successfully used for filling more than 100,000 syringes for Phase 3 clinical trial



Strategic Drug Development Consulting Services

Strategy & execution towards commercial success

Drug research and development is a long-term, high risk and complex process. Scinai has vast experience in developing and executing pre-clinical and clinical plans for recombinant proteins. We offer flexible, professional, and efficient drug development services.

- Immunotherapeutic proteins and infectious disease therapies and vaccines from bench through Phase 3 results
- Project risk and feasibility assessments
- Sensitivity to investment risk and aggressive timelines
- Consulting to navigate pharmaceutical industry, quality and regulatory requirements
- Strategies for marketing approval, market access, and commercial success

Designed from the start with the ultimate goal in mind

With comprehensive development knowledge, manufacturing and regulatory strategies developed at the beginning helps ensure drug products are acceptable and attractive to regulators, manufacturers, patients, payers and providers.

Certain statements in this communication are forward-looking statements ("FLS") within the meaning of the Private Litigation Reform Act of 1995, which involve known and unknown risks, uncertainties, assumptions and other factors which may cause the actual results, performance, or achievements of Scinai Immunotherapeutics Ltd. ("the Company") to be materially different from any results, performance, or achievement expressed or implied by such FLS. Please refer to the Company's SEC filings for a discussion of some risks (including those set forth in the list of risk factors set forth in such filings) that could cause actual results, performance, or achievements of the Company to differ materially from those expressed or implied in such FLS. The Company undertakes no obligation to update or revise any such FLS. | Visit www.scinai.com for details | ©2024

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Boutique end-to-end CDMO

- Strategic drug development consulting services
- Upstream and Downstream process development and Scale-Up
- Analytical method development
- Quality assurance with robust QMS
- cGMP manufacturing
- Aseptic filling and visual inspection

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