# SCINAI Boutique end-to-end CDMO in Israel

**Serving pharmaceutical, biotech and alternative protein food tech companies with pilot and clinical process development and manufacturing**

## cGMP Manufacturing

Manufacturing suites include clean rooms for:

- Upstream fermentation
- Downstream purification
- Media and buffer prep
- Automatic aseptic filling to vials and PFS
- Labeling and visual inspection

- Site designed to meet EMA and FDA GMP standards
- Previously 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:

- Manufacturing process development & scale-up
- Analytical methods development
- In process controls and product release testing

## Deep Pharma Experience

In-house expertise includes:

- 20 years of recombinant protein process development from bench to Phase 3
- cGMP manufacturing from preclinical through Phase 3 clinical trials
- Startup and big pharma leadership in USA, Israel, Europe, China, and Singapore

**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 ~**

## Assets include:

- GMP-ready production clean rooms (EMA and Israel MoH)
- Aseptic fill and finish for clinical trials and pilot scale manufacturing
- Ambr® 250, 2L and 5L fermentors for upstream process development & optimization
- 30L and 300L fermentors for GMP production
- Downstream GMP production: ÄKTA process™, BPG columns, Single use mixer
- Analytic tools
- Water for injection (WFI) utility
- Media and buffer preparations
- And more!

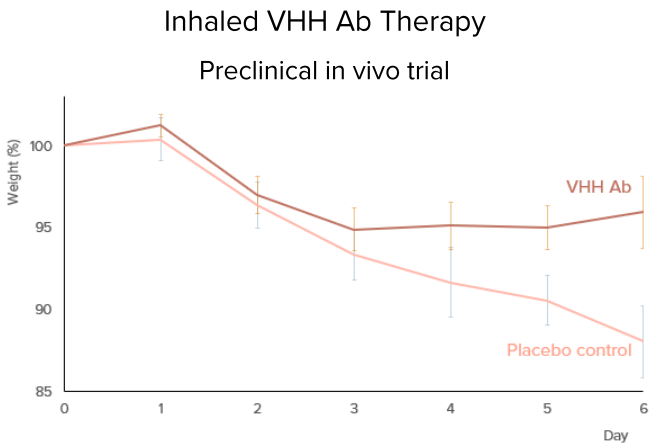
**www.scinai.com/cdmo**

# Proven Development & Manufacturing Success

- **Decades of accumulated 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

## Development and Production of VHH Antibody from Scratch

- In 2022, Scinai received VHH antibody candidates for an inhaled COVID-19 treatment
- Within **only four months**, the team developed, optimized, purified, and upscaled the VHH Abs to manufacturing in our 300L fermentor using a *Pichia pastoris* expression system
- The product was used for a **successful preclinical in vivo proof-of-concept study**




## Scale-up, Production, cGMP Fill and Finish for Phase 3 Clinical Trial

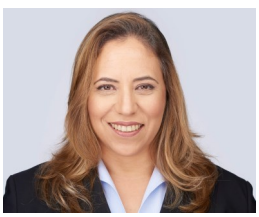
- Successful in-house development of recombinant protein vaccine candidate
- Drug substance scale-up and tech transfer to Scinai
- European QP and Israel MoH previously approved facility for Phase 3 cGMP fill & finish cGMP fill & finish of PFS for 12,400 participant Phase 3 trial

## 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**
*VP Technical R&D*
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 for cell and gene processes
- Built to meet FDA and EMA cGMP manufacturing standards
- Fully segregated air system for every room
- Fully equipped suites with equipment including 30L and single-use 300L fermentors, continuous centrifuge, AKTA process, columns, single use mixers, and powder transfer systems
- Cleaning suite with industrial pharma grade dish washer, industrial autoclave and replated material preparation
- Utilities for production such as 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

**Maxim Leykin BSc (Eng)**
*Head of Engineering*
Engineering project management and maintenance leadership with Omrix, Intel, SodaStream

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

# Upstream Process Development and Scale-up

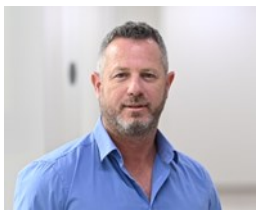
## Fermentation Process Development

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


- Ambr® 250 system with four individual fermentor modules
- The Ambr system 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



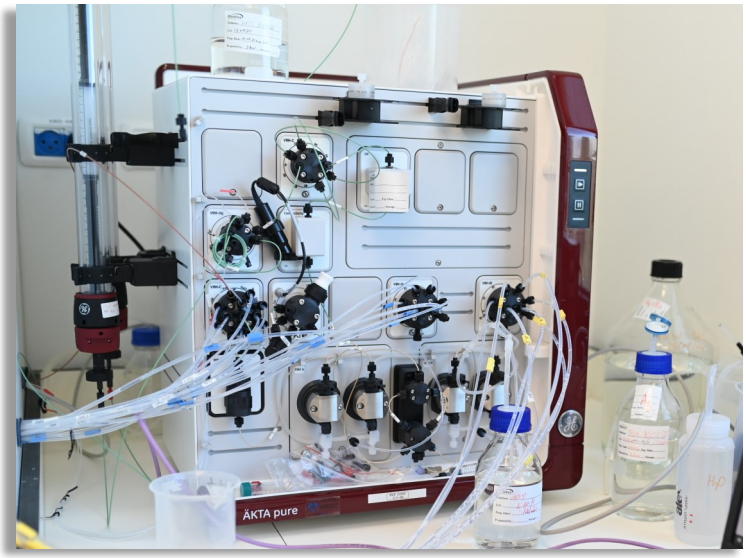
**Zohar Gadri, MSc**
*Technical R&D Upstream Process Team Leader*
Production processes development and protein purification from laboratory to GMP conditions

# 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
- Small-scale resins and chromatography screening for process characterization, optimization, efficiency, and purity
- Clarification – Variety of dead-end and TFF filtration skills
- TFF - Wide range of hollow fiber and cassettes for UFDF processes
- ÄKTA readyflux™, ÄKTA pure™ 150, ÄKTA pilot, and ÄKTA process™, Sartoflow® Smart TFF System, for countless optional purification procedures
- Columns up to 50L




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

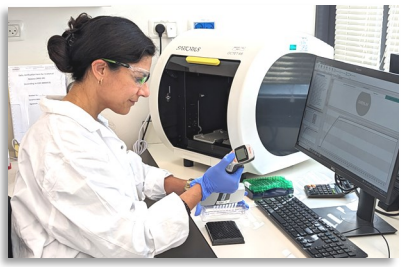
**Navah Figov, MSc**
*Technical R&D Downstream Process Team Leader*
Expertise in downstream process including both developing purification and scale-up processes for GMP pharmaceutical manufacturing

# Analytical Method Development and Quality (QC & QA)

Scinai CDMO's experienced team of scientists and state-of-the-art facilities ensure accuracy and reliability of analytical characterization, quality control and quality assurance services. Our boutique service includes custom packages for innovative and biosimilar 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 affinity binding (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 drug'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
- Filling machine can be adapted for various vials and syringe types and volumes
- Fully equipped supporting suites
- Successfully used for filling more than 100,000 syringes for Phase 3 clinical trial

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## www.scinai.com/cdmo