

2000 Hamilton Street Suite 204 Philadelphia, PA 19130 (215) 241-9760 Fax (215) 241-9684

"Innovative Therapies for Cancer and Other Diseases"

AVAX Technologies, Inc. 2000 Hamilton Street, Suite 204 Philadelphia, PA 19130 T# 215-241-9760, ext. 302 F# 215-241-9684

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January 23, 2006

Licensing Assistant Section Nuclear Materials Safety Branch U.S. Nuclear Regulatory Commission, Region 1 475 Allendale Road King of Prussia, PA 19406-1415

030 34 903

Subject: Amendment to NRC Form 374, Materials License #37-30489-01

To Whom It May Concern:

In accordance with 10 CFR 30.38, the following is an amendment request to NRC Form 374, Materials License #37-30489-01.

The only change requires a name change in line item #12 from Craig E. Broecker to Henry E. Schea III. All other items are unchanged. Craig is no longer considered the Radiation Safety Officer (RSO) for AVAX Technologies, Manufacturing Facility, Philadelphia, PA.

Henry has assumed the responsibilities as the RSO effective on 01/23/2006. The following attachments include a copy of his resume.

In an effort to establish the validity for this amendment change request, the President and Chief Operating Officer of AVAX Technologies, Inc. has reviewed this document and supporting attachments.

Reviewed by: <u>Richard Ramey</u> Date: 0//25/06 Richard P. Rainey, CPAO

Sincerely,

Henry E. Short

Henry E. Schea III Director, Global Quality and Regulatory Affairs Enclosure: Copy of Henry E. Schea's resume

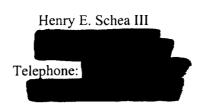
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Objective

Identify an opportunity that will allow me to use my talents and experience in a challenging position. I desire to work in an exciting company that is actively involved in ensuring and improving human health.

Qualifications

- Twenty-five years in the manufacture and development of CBER licensed pharmaceuticals including: vaccines, antibodies, recombinant proteins, gene medicines and diagnostics.
- Demonstrated proficiency communicating with the FDA through IND/IDE/NDA/BLA filings and licensing and distribution of approved products.
- Technically competent in Validation Master Planning and validation of processes, equipment, facilities and analytical methods for the testing and manufacture of biopharmaceuticals.

Employment History

AVAX Technologies, Inc., Director, Quality Systems	Philadelphia, PA	March 2002- Present
DuPont Pharmaceuticals, Director, GMP Compliance	Wilmington, DE	July 2000 - December 2001
Chimeric Therapies, Inc, Director, Quality Systems	Sharon Hill, PA	March 1997 - July 2000
GeneMedicine, Manager, QA/QC	The Woodlands, TX	February 1994 - February 1997
Hybritech,	San Diego, CA. (A divi	-
Research Scientist, Technical S	upport	October 1991 - January 1994
Amgen, Supervisor, Clinical QC-Metho Supervisor, Process Developme Lead, Clinical Manufacturing	Thousand Oaks, CA. ds Development	October 1991 - January 1994 May 1981 - September 1991
Amgen, Supervisor, Clinical QC-Metho Supervisor, Process Developme	Thousand Oaks, CA. ds Development	-

Education

Trained and Certified, Eli Lilly and PDA: Management, GMP, TQM, Statistical Process Control, Materials Control, Clean Room Design & Monitoring, Change Control and Audits

University of Mass, Amherst, Amherst, MA. BS, Microbial Genetics December, 1976

Professional Organizations ASQ, PDA, ASTM

PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

Professional Experience

AVAX Technologies, Inc. Director, Quality Systems

Reporting to President, COO Current responsibilities

> · Successfully lead the manufacturing, quality and engineering teams in developing a response to an FDA clinical hold and gained FDA approval to re-initiate 2 clinical trials.

· Identify viable opportunities to expand business opportunity through manufacturing contracts.

DuPont Pharmaceuticals Director, GMP Compliance

Reporting to Senior Director, ABT

July 2000 - December 2001

March 2002 - Present

· Lead the development of a diagnostic device.

Chimeric Therapies, Inc Director, Quality Systems

Reporting to Chief Operating Officer

- · Hire a Quality Control Department and develop appropriate QC testing systems as needed for the company's stage of development (pre-clinical through Phase II/III).
- · Hire a Quality Assurance Department and build systems appropriate to the company's stage of development (pre-clinical through Phase II/III).
- Develop and administer Validation Master Plan for quality, manufacturing and facility.

GeneMedicine Manager, Quality Assurance/Quality Control

Reporting to VP, Clinical and Regulatory Affairs

- · Design, build and commission a manufacturing and research facility from a green site on time and on budget. This was performed in cooperation with the Manufacturing Director and an engineering firm.
- Develop and administer Validation Master Plan for quality, manufacturing and facility.
- · Manage and direct all aspects of QA/QC. This includes creation and implementation of an SOP system, in-house training program, internal and external auditing and creation and administration of a Validation Master Plan.
- · Assemble, organize and write Chemistry, Manufacturing and Control section of IND's.

Hybritech Operations Representative, Imaging Project Team

Reporting to VP of Operations

- September 1993 January 1994 · Establish and validate a CBER licensable manufacturing facility for In-111 Labeled Anti-CEA MoAb ZCE025.
- · Assist in writing and implementation the Validation Master Plan for the facility.
- · Develop QC assays including RIA and RRA assays with I-125 labeled antibodies
- Reduce COPS by 15% with a program to reduce scrap, obsolescence and inventory.

Research Scientist, Manufacturing Technical Support

October 1991 - September 1993

· Supervise a team of 5 scientists.

Reporting to Director of Operations

- · Represent QC and Manufacturing during the pre-license inspection.
- · Prepare manufacturing, QC and engineering for the FDA pre-license inspection.
- · Interim Radiation Safety Officer for MTS.

Amgen Supervisor, Analytical Development, Recovery Process Development

Reporting to Director, RPD

November 1981 - September 1991

- Supervise a team of 6-7 chemists.
- · Develop and validate analytical methods for product characterization including:
 - · Hybridizations using P-32 labeled DNA/RNA fragments for blots and sequence analysis.
 - · Analysis of cellular physiology using S-35, C-14 and H-3 biological markers.

Patents

· I am co-inventor on three patents, Patent #'s D339,869, D332,397 and 5,181,394.

March 1997 - July 2000

February 1994 - February 1997

This is to acknowledge the receipt of your letter/application dated

1/23/2006, and to inform you that the initial processing which includes an administrative review has been performed.

There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

138308 Your action has been assigned Mail Control Number When calling to inquire about this action, please refer to this control number. You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI) (6-96)

Sincerely, Licensing Assistance Team Leader