AVAX TECHNOLOGIES, INC.

2000 Hamilton Street
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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

NMSB 3

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

03034903

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: Richard Rainey Date: 01/25/06
Richard P. Rainey, CPA

Sincerely,

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

138308

NMSS/RGN1 MATERIALS

Henry E. Schea III
[redacted]
Telephone: [redacted]

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., Philadelphia, PA March 2002- Present
Director, Quality Systems

DuPont Pharmaceuticals, Wilmington, DE July 2000 - December 2001
Director, GMP Compliance

Chimeric Therapies, Inc, Sharon Hill, PA March 1997 - July 2000
Director, Quality Systems

GeneMedicine, The Woodlands, TX February 1994 - February 1997
Manager, QA/QC

Hybritech, San Diego, CA. (A division of Eli Lilly)
Research Scientist, Technical Support October 1991 - January 1994

Amgen, Thousand Oaks, CA. May 1981 - September 1991
Supervisor, Clinical QC-Methods Development
Supervisor, Process Development
Lead, Clinical Manufacturing

The Salk Institute, San Diego, CA. October 1979 - May 1981

Eunice Kennedy Shriver Center, Waltham, MA. April 1977 - September 1979

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

Professional Experience

AVAX Technologies, Inc. Director, Quality Systems
Reporting to President, COO March 2002 - Present
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
- Lead the development of a diagnostic device.

Chimeric Therapies, Inc Director, Quality Systems
Reporting to Chief Operating Officer March 1997 - July 2000
- 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 February 1994 - February 1997
- 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
Reporting to Director of Operations October 1991 - September 1993
- Supervise a team of 5 scientists.
- 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.

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.

AMEND. 37-30489-01

☑ 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

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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.

Your action has been assigned **Mail Control Number** 138308.
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