U.S. FOOD & DRUG
ADMINISTRATION

U.S. Food and Drug Administration
Kansas City District Office
8050 Marshall Drive – Suite 205
Lenexa, KS 66214
(913) 495-5100

October 25, 2016

Ms. Kathryn M. Grayson, CEO
EKG Life Science Solutions LLC
4633 World Parkway Circle
Suite 107
St. Louis, MO 63134

Dear Ms. Grayson:

The U.S. Food and Drug Administration (FDA), or a state agency contracted by FDA, conducted an inspection at your location ending on June 15, 2016. Effective April 1, 1997, when the Agency determines an inspection is closed under 21 C.F.R. 20.64 (d)(3), FDA releases a copy of the inspection report to the inspected firm. Please note that FDA will not provide a copy of a state inspection report or summary through this process if the firm was provided a copy at the close of the state's inspection.

Unless provided at the close of the inspection, you will find a copy of the inspection report or summary attached. FDA may have redacted some information in accordance with the Freedom of Information Act (FOIA) and Title 21, Code of Federal Regulations, Part 20. Firms may request a copy of their FDA inspections completed prior to April 1, 1997 through FOIA.

FDA is working to make its regulatory process and activities more transparent to the regulated industry. Part of this effort is releasing a copy of your inspection report or summary to you, or acknowledging that the state provided you a copy at the close of their inspection.

Please contact Miguel Hernandez, Director of Compliance Branch, at (913) 495-5101 should you have any comments or questions

Sincerely,

Miguel A. Hernandez
Director, Compliance
Kansas City District

KAN: 3010232943

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SUMMARY

This GMP inspection of a registered control testing laboratory was conducted in accordance with CPGM 7356.002 "Drug Manufacturing Inspections" as part of the KAN-DO FY16 work plan. This assignment was issued under FACTS ID 11572790 and MARCS ID 24187.

This was the initial FDA inspection.

Current inspection covered the Quality and Laboratory Controls System and included a review of the operations of the quality control unit, training, sample receiving and handling, out of specifications (OOSs), deviations, equipment qualification and calibration. The analytical testing of medical devices was not covered during the inspection. This inspection found the firm operates as a control testing laboratory performing method development/validation and reference standard characterization for pharmaceutical products and extractable/leachable, impurity identification, and degradation testing for medical devices according to their clients requests.

No FDA 483, Inspectional Observations, was issued and no objectionable conditions were observed.

There were no refusals and management was cooperative. No samples were collected during the inspection.

Management was warned of their responsibility to adhere to the Food, Drug, and Cosmetic Act.

ADMINISTRATIVE DATA

Inspected firm:	EKG Life Science Solutions
Location:	4633 World Parkway Cir Ste 107 Berkeley, MO 63134-3115
Phone:	-+810-354-5229
FAX:	
Mailing address:	

Dates of inspection:	6/13/2016-6/15/2016
Days in the facility:	3
Participants:	**Tiara N Brown-Crosen, Investigator**

Upon arrival Credentials were presented and FDA-482, Notice of Inspection, was issued to Kathryn M. Grayson, CEO. Mrs. Grayson confirmed that she is the most responsible person on site.

No FDA-483, Inspectional Observations, was issued.

HISTORY

EKG Life Science Solutions, LLC was established in March 2013 by Jennifer Eagan, Allen S. Kesselring, and Kathryn M. Grayson. The firm performs chemistry, manufacturing, and controls (CMC) support and research and development for medical devices and pharmaceuticals.

The firm currently has 4 employees; 2 full-time, 1 contract, and 1 summer intern. The firm's office hours are Monday through Friday, 8:00am to 4:30pm. The firm is approximately 1,100 square feet and contains an office area, storage area, and laboratory (See **Exhibit 1,** Facility Diagram). The firm's drug registration is current.

POST INSPECTIONAL CORRESPONDENCE

Correspondence should be addressed to:
EKG Life Science Solutions, LLC
Kathryn M. Grayson, CEO
4633 World Parkway Circle, Suite 107
St. Louis, MO 63134

INTERSTATE COMMERCE

EKG Life Science Solutions, LLC performs chemical analysis on human and veterinary drugs products and components, medical devices, and active pharmaceutical ingredients. The firm provided a list of their current customers (**exhibit 2**) and approved subcontracted labs (**exhibit 3**).

Ms. Eagan stated approximately 100% of the regulated products tested are shipped in interstate commerce.

JURISDICTION

The firm provided a list of current drug products, APIs, and medical devices tested by the firm (**exhibit 4**).

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Kathryn M. Grayson, Chief Executive Officer: According to Mrs. Grayson she is the most responsible person at the firm. Mrs. Grayson has one direct report and has hire/fire authority. Mrs. Grayson duties consist of but are not limited to sales activities, developing proposals, and budgeting. Mrs. Grayson was available throughout the inspection and provided some information contained in this report.

Jennifer Eagan, Director of Quality and Regulatory: Ms. Eagan stated her duties consist of overseeing the quality department, the final review of reports, protocols, methods, change controls, and investigations, and performing internal/external audits. Ms. Eagan accompanied me throughout the inspection and provided majority of the information contained in this report.

Allen S. Kesselring, Chief Science Officer: Mr. Kesselring currently has two full-time employees and an intern that reports directly to him. He stated he has hire/fire authority. Mr. Kesselring duties consist of but are not limited to overseeing analytical operations, training of laboratory staff, and technical review of projects. Mr. Kesselring was available throughout the inspection and provided majority of the laboratory information contained in this report.

An organizational chart for the firm is attached (**Exhibit 5**).

FIRM'S TRAINING PROGRAM

I reviewed procedure no. 1003 "Training" (version 1, effective 12/17/2013). The firm provides training sessions including an assessment quiz on standard operating procedures (SOPs), safety, regulatory, and laboratory. New and current employees receive on-the-job training regarding their specific duties. Continuous training for employees include the following: SOPs, instrument training, method training, cGMP, and blood-borne pathogen. I reviewed training records for laboratory analysts [redacted] and [redacted]. No deficiencies were found.

MANUFACTURING/DESIGN OPERATIONS

Quality System

The roles and responsibilities of the quality control unit (QCU) are outlined in the firm's procedure no. 2000 "Quality Assurance" (version 1, effective 10/08/13). Quality Assurance is responsible for approving all quality related activities including but not limited to: investigations; analyses;

deviations; change controls; equipment qualifications; corrective and preventative actions (CAPAs); complaints; standard operating procedures (SOPs); standard testing methods (STMs), protocols; employee training; pest control; subcontracted laboratories and critical vendors. The firm performs annual quality internal audits and general laboratory audits quarterly, at minimum. No significant deficiencies were found in regards to quality activities.

The firm does not perform Annual Product Reviews (APRs).

I reviewed the firm's procedure no. 1009 "Deviations" (version 2, effective 05/19/2016) for reporting deviations. Deviations apply to written procedures and processes and are classified as major and minor. Major deviations have the potential to directly impact test results, while minor deviations do not have the potential to directly impact test results. Quality Assurance is responsible for handling all deviations. The firm provided a list of deviations from 2013 to present. I reviewed the following deviations related to [redacted] and noted no significant deficiencies:

- Deviation D160003 which was opened due to three samples used for accuracy instead of one sample.
- Deviation D160004 which was opened due to a change in how precision is executed.

The firm has established written procedure no. 1008 "Change Control" (version 1, effective 04/30/2014) for controlling changes to internal documents and qualified equipments. I reviewed change control CR150006 for the installation, operation, and performance of an environmental controlling device. No deficiencies were found.

Samples involved in deviations or investigations, incoming samples, and samples awaiting final disposition are held in quarantine. The cabinet used for quarantine products is held under lock and key.

The firm does not perform any reprocessing and reworking.

The firm does not have a procedure for handling returns.

Laboratory Controls System

Allen S. Kesselring, Chief Science Officer, oversees the laboratory. The Quality Control (QC) laboratory consist of 3 employees, including 2 full-time lab analyst and 1 summer intern. The QC laboratory is responsible for chemical testing of raw materials, active ingredients, drug products, and packaging materials. The laboratory appeared to be adequately staffed to handle the workload. I reviewed the training records for lab analysts [redacted] and [redacted] All employees appear to be adequately trained.

Incoming samples are held in the designated quarantine area and tracked in a receiving sample notebook. The information documented in the sample notebook includes: sample ID; sample description; lot number; number of units; storage conditions; received by initials/date. I reviewed the

sample receipt notebook and no significant deficiencies were noted.

The firm provided a full list of equipment and instruments (**Exhibit 6**). I reviewed the firm's laboratory equipment calibration schedule. All equipment was labeled and calibrations were current. The laboratory appeared to have adequate equipment and facilities for the intended testing.

The firm has six computers dedicated to specific laboratory instruments. Each employee has an unique username and password. I reviewed protocol P150003 version 1"Installation, Operation, and Performance Qualification of a Nicolet Avatar 360 FTIR with HATR Accessory." I verified the appropriate reference standards were controlled, used and stored properly, raw data compared to reported data, and observed login procedure for the OMNIC software used for FTIR. I also reviewed the FTIR equipment use and maintenance logbook. No significant deficiences were noted.

The firm uses USP methods and conducts method transfers from their client methods. Quality Assurance performs a compliance check of all applicable USP methods, protocols, and procedures used for testing.

I reviewed the firm's procedure 3002 "Investigations" (version 1, effective 09/25/13) for performing formal laboratory investigations of results. The firm had one drug product investigation from 2013 to present. I reviewed investigation I160002 due to accuracy failing during the validation of [redacted]. No significant deficiences were noted.

The firm does not conduct any stability testing.

COMPLAINTS

I reviewed procedure no. 1010 "Complaints" (version 1, effective 08/23/13) for the receipt, handling, and resolution of written and oral complaints. Management stated they have not received any quality or health related complaints. No FACTS Complaints were received against the firm to date of inspection.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

A Form FDA 483, Inspectional Observations, was not issued.

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

During the close-out meeting the following persons were present: Kathryn M. Grayson, CEO; Jennifer Eagan, Director of Quality and Regulatory; Allen S. Kesselring, Chief Science Officer. No FDA-483 was issued to management, nor were there any verbal observations. Management was warned of their responsibilities to adhere to the FD&C Act.

SAMPLES COLLECTED

No samples were collected.

VOLUNTARY CORRECTIONS

This was the initial FDA inspection. There were no voluntary corrections to verify.

EXHIBITS COLLECTED

1 Facility Diagram, 1 page
2 Client List, 1 page
3 Approved Subcontracted Labs and Critical Vendors, 4 pages
4 Product List, 1 page
5 Organizational Chart, 1 page
6 Laboratory Equipment List, 3 pages

ATTACHMENTS

I FDA 482, Notice of Inspection, 3 pages

8/11/2016

X Tiara N Brown-Crosen

Tiara N Brown-Crosen
Investigator
Signed by: Tiara N. Brown-crosen -S