Professional Resources

One does NOT need to be a member of NCRAF to list a resource to this page.
Listings will generally be posted within 48 hours of submission.

On this page you will find an alphabetical listing of companies who have the skills and knowledge you may want to access to address your regulatory questions.

Company
Type
Contact Information

All Safe Records Management Solutions Inc.

www.allsaferecords.com

Document Shredding And Imaging Services

Susan Meeker

susan@allsaferecords.com

919-201-5073

Secure onsite document shredding available. We bring our mobile shred truck to your home or business

DTS Language Services

www.dtstranslates.com

Certified Translation Services

Duncan Shaw

dshaw@dtstranslates.com

919-582-0330

Certified Translations of Regulatory and Life Sciences documents in over 100 languages. 24/7 Telepho

Edgerton Data Consulting

www.edgerton-data.com

Biometrics Project Management

Dawn Edgerton

dawn@edgerton-data.com

(919) 270-3100

Edgerton Data Consulting works with small to mid-size companies that do not have a full-time staff and i

Specialties include : * Finding the best CRO for your clinical trial for data management, CDISC, and
* Sponsor representation at key clinical trial project team meetings * Project management * Vendor gove
* Contract negotiation and pricing * Communications and relationship management * SOP and work inst

FDA Consulting, LLC

www.fda-consultingllc.com

Regulatory Consultancy

Michael Wienholt

michaelwienholt@icloud.com

(760) 532-6304

FDA Consulting, LLC specializes in global regulatory strategies, submissions and quality management

Focus 42, LLC

www.focus42.net

Medical Device Software Consulting

Yuan Xu

focus42consulting@gmail.com

919-360-3488

Focus 42 provides consulting expertise for Medical Device SOFTWARE DEVELOPMENT, In Vitro

- **Regulatory Strategy and Submission in US, Canada, EU, and China.**
- **FDA Warning Letter/483s Remediation**
- **Streamline the Quality Management System using the least burden approach.**
- **Provide Solutions for UDI requirements, Cybersecurity, Risk Management (etg., Continuous De**
- **Device Registration and Listing**

KC Biopharma

www.kcbiopharma.com

Regulatory Consultancy

Kamali Chance, PhD, MPH, RAC

Kamali@KCBiopharma.com

919-667-8507

Dr. Kamali Chance is a highly experienced regulatory professional ready to assist your organization in: *

Dr. Chance’s tenure, in addition to supporting 505(b)(2) regulatory strategy and dossier preparation, incl

Lindsey Regulatory Affairs Consulting, LLC

www.lracs.com

Regulatory Consulting

Sequita Lindsey

contact@lracs.com

919-316-8037

Lindsey Regulatory Affairs Consulting, LLC (DBA, LRA Consulting) strives to meet the needs of the clien

Oneresouce Regulatory

www.onesourceregulatory.com

Regulatory Consulting

Tracy Rockney

tracy@onesourceregulatory.com

610-283-3067

Regulatory Advertising & Promotion Review; Medical Review (advertising and promotion, independent s

Polaris Compliance Consultants, Inc.

www.polarisconsultants.com Quality Compliance Consultants Celine Clive

CMClive@polarisconsultants.com

919-463-0003 X111

Polaris Compliance Consultants, Inc. has 15 years experience in supporting quality and compliance

Auditing **Writing**

Quality & Regulatory Consulting, LLC

www.qandrconsulting.com

Regulatory Affairs; Quality Systems

James Clinton

jclinton@QandRConsulting.com

919-247-0479

Compliance and Remediation: FDA 483 / Warning Letter response, Strategic planning to sustainably c

Regulatory Affairs, North America, Inc.

www.ranainc.com

Regulatory Consultancy

Nancy Chew

nchew@ranainc.com

919-479-9956

Regulatory strategy - full registration plans t**Regulatory Research** - literature and/

S2 Lingua

www.s2lingua.com

Certified Translation Services For Regulatory And Medical Documentation

Matt Schexnayder

info@s2lingua.com

919-709-3119

S2 Lingua translates medical and clinical trial documentation for CROs, pharma, biotech, and medical

SFP Consulting, LLC

www.sfpconsulting.com

Regulatory Writing, Consulting, and Training

Susan Sisk, PhD, RAC

susan.sisk@sfpconsulting.com

919-338-2785

SFP Consulting, LLC (S[illegible] Sisk, PhD, RAC) speciali[illegible] **Writing and review services** [illegible] **Consulting Services** [illegible]

Dr. Sisk has experience in the following therapeutic areas: neurology, oncology/carcinogenesis, gastroin

Temple University's School of Pharmacy

RA and QA Graduate Program

https://pharmacy.temple.edu/raqa

Education Opportunities

QARA@temple.edu

1-267-468-8560

Temple University has outstanding graduate programs in Regulatory Affairs and Quality Assurance. Ou