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freelance your team

Access on-demand expertise & resources from our top-tier healthcare industry independent consultants & interim managers

Our Projects & Profiles in Regulatory Affairs

Air Liquide · astellas · Boehringer Ingelheim · DIGIPHARM · GSK · Pierre Fabre · QIAGEN · Seagen

Our Expertise

Regulatory Affairs

Training
Registration
Advertising law, Sunshine
Compliance
...

Audits & Compliance
Internal & External audits
Preparation & Corrections
...

RA Hotline

New market Authorization Registration
FR / EU / International (ANSM, EMA, FDA...)
Ph, Medical devices, cosmetic
Strategy
MA dossiers preparation
Authorities submission & follow up
Technical-regulatory & market access strategy
...

Post Market Authorization activities
Variations (quality, administrative & safety)
Renewals
PV activities (PASS/PAES)
Strategy
MA dossiers update
Authorities submission & follow-up
...

Regulatory requirements
Declarations management & Authorization applications : anti-gifts & transparency
Promotional materials, advertising control & submission
...

Regulatory & normative requirements definition & intelligence
Compliance with EU & International guidelines
...

Risk assessment & analysis

Interim Management
Transition Manager
RA Manager
RA project Manager
RA Associate
CMC Manager
...

Usability Dossier

Regulatory Databases update
(GED, tracking...)

Labelling

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Our Projects

Regulatory Affairs

Regulatory Expert – CRO

Need : Readibility user testing (deliverable)

Expert : Polish regulatory freelance expert

Duration : 1 month, part-time

Regulatory Expert – Consulting

Need : Looking for an expert to prepare & submit the regulatory dossier of a BLA for US FDA (ressource)

Expert : US Freelance expert in BLA & IND submission for US FDA

Duration : 3 months, full-time

Regulatory Manager – Biotech

Need : Looking for an expert to elaborate the EMA regulatory strategy for a new product launch (ressource)

Expert : Freelance expert in EMA regulatory strategy

Duration : 6 months, full-time

Regulatory Expert – MedTech

Need : Looking for an expert to prepare and submit a regulatory CE marking & reimboursment dossier (ressource)

Expert : Regulatory Freelance expert in CE marking dossier & submission

Duration : 4 months, full-time

Our Freelance Experts

Regulatory Affairs

Hanna
Regulatory Affairs
Germany

Franck
Regulatory Affairs
France

Jackson
Regulatory Affairs
Switzerland

Véronique
Regulatory Affairs
France

Regulatory Affairs

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Hanna
REGULATORY AFFAIRS FREELANCE EXPERT

Freelance Regulatory Affairs Independent

"I 'm a very experienced freelance Regulatory Affairs Expert (more than 10 years), specialized especially in CMC, submissions and labelling."

> MY IDENTITY

Diploma / Background :
University of Hamburg-
Rechtswissenschaft (Law),
Bachelor Professional of Pharmaceutical Production and Management (CCI) ,
pharmaceutical Production and Management (Industriemeister - Fachrichtung Pharmazie),
G13 Hamburg PTA / Pharmacy Technician,
Berufsfachschule PTA

Nationality : German
Country : Germany

Languages : German, English

Experience Level : Experience > 10 years

Companies / Clients : Freelance (LTS Lohmann Therapie-Systeme, Heraeus), Roche, STADA Group, Beiersdorf, Johnson & Johnson, Bodechemie, Fair-Med Healthcare, Saidia Pharma Services Ltd.

> MY CONDITIONS

Indicative rate:

Remote Flexible : Yes

Travel Flexible : Yes

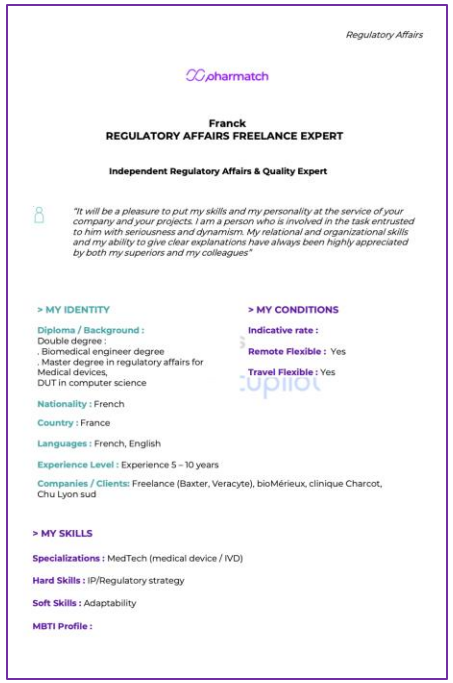
> MY SKILLS

Specializations : Pharma (pharmaceutical / BigPharma)

Hard Skills : CMC program

Soft Skills : Accurate

MBTI Profile : INTP



Regulatory Affairs

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Franck
REGULATORY AFFAIRS FREELANCE EXPERT

Independent Regulatory Affairs & Quality Expert

"It will be a pleasure to put my skills and my personality at the service of your company and your projects. I am a person who is involved in the task entrusted to him with seriousness and dynamism. My relational and organizational skills and my ability to give clear explanations have always been highly appreciated by both my superiors and my colleagues"

> MY IDENTITY

Diploma / Background :
Double degree :
. Biomedical engineer degree
. Master degree in regulatory affairs for Medical devices,
DUT in computer science

Nationality : French

Country : France

Languages : French, English

Experience Level : Experience 5 – 10 years

Companies / Clients: Freelance (Baxter, Veracyte), bioMérieux, clinique Charcot, Chu Lyon sud

> MY CONDITIONS

Indicative rate :

Remote Flexible : Yes

Travel Flexible : Yes

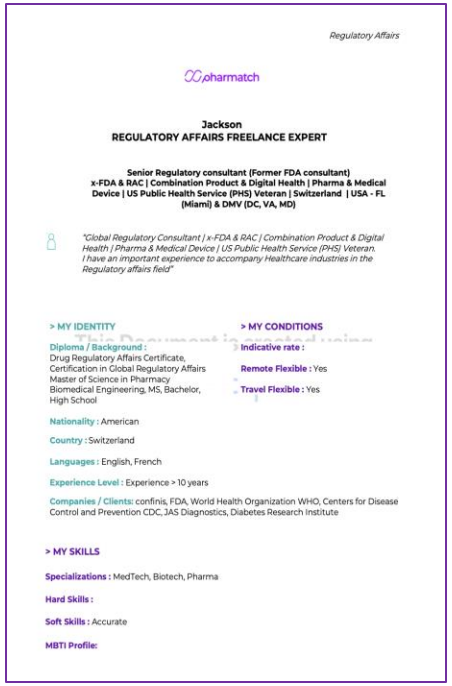
> MY SKILLS

Specializations : MedTech (medical device / IVD)

Hard Skills : IP/Regulatory strategy

Soft Skills : Adaptability

MBTI Profile :



Regulatory Affairs

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Jackson
REGULATORY AFFAIRS FREELANCE EXPERT

Senior Regulatory consultant (Former FDA consultant)
x-FDA & RAC | Combination Product & Digital Health | Pharma & Medical Device | US Public Health Service (PHS) Veteran | Switzerland | USA - FL (Miami) & DMV (DC, VA, MD)

"Global Regulatory Consultant | x-FDA & RAC | Combination Product & Digital Health | Pharma & Medical Device | US Public Health Service (PHS) Veteran. I have an important experience to accompany Healthcare industries in the Regulatory affairs field"

> MY IDENTITY

Diploma / Background :
Drug Regulatory Affairs Certificate,
Certification in Global Regulatory Affairs
Master of Science in Pharmacy
Biomedical Engineering, MS, Bachelor,
High School

Nationality : American

Country : Switzerland

Languages : English, French

Experience Level : Experience > 10 years

Companies / Clients: confinis, FDA, World Health Organization WHO, Centers for Disease Control and Prevention CDC, JAS Diagnostics, Diabetes Research Institute

> MY CONDITIONS

Indicative rate :

Remote Flexible : Yes

Travel Flexible : Yes

> MY SKILLS

Specializations : MedTech, Biotech, Pharma

Hard Skills :

Soft Skills : Accurate

MBTI Profile:

Regulatory Affairs

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Véronique
REGULATORY AFFAIRS FREELANCE EXPERT

Quality Assurance & Regulatory affairs Independent expert, Responsible Pharmacist

"Many years of experience in Quality assurance and Regulatory affairs in the Healthcare industry"

> MY IDENTITY

Diploma / Background :
PhD Pharmacist Doctor

Nationality: French

Country : France

Languages : French, English

Experience Level : Experience > 10 years

Companies / Clients : Indépendant (LFFB, MSLAB, Ipsen, Novartis), Cellprothera, LABORATOIRE DE L'HOMME DE FER, EUROMEDEX, Lilly, AstraZeneca

> MY CONDITIONS

Indicative rate :

Remote Flexible : Yes

Travel Flexible : Yes

> MY SKILLS

Specializations: Pharma, MedTech

Hard Skills: CAPA

Soft Skills: Adaptability

MBTI Profile:

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