The fifteen statutory roles in German pharma and medtech

Every named appointment the law requires: legal basis, who must appoint it, and the qualification demanded.

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	ROLE	LEGAL BASIS	WHO MUST APPOINT IT	QUALIFICATION THE LAW REQUIRES
1	**Sachkundige Person** Qualified Person	§§ 14, 15 AMG	Every holder of a manufacturing authorisation	Named degree plus practical experience, both spelled out in § 15 AMG
2	**Leiter der Herstellung und Leiter der Qualitätskontrolle** Head of Production and Head of Quality Control	§ 12 AMWHV, EU GMP Guide Chapter 2	Every manufacturing site	No named degree. Documented responsibility and independence from each other
3	**Stufenplanbeauftragter** Graduated Plan Officer	§ 63a AMG	Pharmaceutical entrepreneurs placing finished medicines on the German market	Expertise not defined in law, assessed case by case. Residence in an EU member state
4	**Informationsbeauftragter** Information Officer	§ 74a AMG	Pharmaceutical entrepreneurs placing finished medicines on the market	Expertise and reliability, not defined in law. In practice a science degree and close work with the Fachinformation
5	**Verantwortliche Person (Großhandel)** Responsible Person, wholesale distribution	§ 52a AMG, EU GDP guidelines	Every holder of a wholesale distribution licence	Expertise matched to the products and the operation. No pharmacy degree required
6	**Verantwortliche Person (Gewebeeinrichtung)** Responsible Person, tissue establishment	§ 20c AMG	Tissue establishments processing by non-industrial methods	Medicine, biology, biochemistry or comparable, plus two years in tissue processing
7	**Sachkundige Person (Tierarzneimittel)** Qualified Person, veterinary medicines	Art. 97 Regulation (EU) 2019/6, TAMG	Every holder of a veterinary manufacturing authorisation	Degree in one of six named disciplines, plus two years of practical experience in authorised manufacturing
8	**Pharmaberater und Pharmareferent** Pharmaceutical Sales Representative	§§ 75, 76 AMG	Any company sending people full-time to inform healthcare professionals about medicines	Three routes: a science degree, technical assistant training, or the examined Pharmareferent qualification
9	**BtM-Verantwortlicher** Controlled Substances Officer	§§ 3, 5, 6, 7 BtMG	Every holder of a controlled substances licence, and separately for each further site in a non-adjacent municipality	Five routes set out in § 6 BtMG, depending on what the company does with the substances
10	**Person Responsible for Regulatory Compliance** PRRC	Art. 15 MDR, Art. 15 IVDR	Every medical device manufacturer and every authorised representative (micro and small enterprises may use an external PRRC)	Degree plus one year in device regulatory or quality work, or four years of that work
11	**Medizinprodukteberater** Medical Device Consultant	§ 83 MPDG	No appointment duty. The requirement sits on the individual doing the work	Relevant training plus product instruction, or one year of relevant work
12	**Beauftragter für Medizinproduktesicherheit** Medical Device Safety Officer	§ 6 MPBetreibV	Health facilities with regularly more than 20 employees	Competent and reliable, with medical, scientific, nursing, pharmaceutical or technical training
13	**Strahlenschutzbeauftragter** Radiation Protection Officer	§ 70 StrlSchG, § 48 StrlSchV	Every operator licensed or notified for work with ionising radiation	Certified Fachkunde for the application area, refreshed at least every five years
14	**Gefahrgutbeauftragter** Dangerous Goods Safety Adviser	§§ 3, 4 GbV, ADR 1.8.3	Any undertaking with duties as a Beteiligter in dangerous goods carriage	IHK Schulungsnachweis for each transport mode, valid five years
15	**Verantwortliche Person (Kosmetik)** Responsible Person, cosmetics	Art. 4, 5 Regulation (EC) 1223/2009	Manufacturers, importers and own-brand distributors placing cosmetics on the EU market	No qualification prescribed. Establishment in the Union and written acceptance of the mandate

Reference summary, not legal advice. Checked 14th November 2026. Licence CC BY 4.0. morethancareer.de/statutory-roles-chart.html

Legal references, with links to the consolidated texts

1. Sachkundige Person
§ 14 Abs. 1 Nr. 1 AMG: www.gesetze-im-internet.de/amg_1976/__14.html
§ 15 AMG: www.gesetze-im-internet.de/amg_1976/__15.html
§ 19 AMG: www.gesetze-im-internet.de/amg_1976/__19.html

2. Leiter der Herstellung und Leiter der Qualitätskontrolle
§ 12 Abs. 1 AMWHV: www.gesetze-im-internet.de/amwhv/__12.html
EU GMP Guide, Part I, Chapter 2 (EudraLex Volume 4): health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

3. Stufenplanbeauftragter
§ 63a AMG: www.gesetze-im-internet.de/amg_1976/__63a.html

4. Informationsbeauftragter
§ 74a AMG: www.gesetze-im-internet.de/amg_1976/__74a.html

5. Verantwortliche Person (Großhandel)
§ 52a Abs. 2 Nr. 3 AMG: www.gesetze-im-internet.de/amg_1976/__52a.html
EU GDP guidelines 2013/C 343/01, Chapter 2.2: eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013XC1123(01)

6. Verantwortliche Person (Gewebeeinrichtung)
§ 20c Abs. 2 Nr. 1 und Abs. 3 AMG: www.gesetze-im-internet.de/amg_1976/__20c.html

7. Sachkundige Person (Tierarzneimittel)
Art. 97 Regulation (EU) 2019/6: eur-lex.europa.eu/eli/reg/2019/6/oj/eng
TAMG: www.gesetze-im-internet.de/tamg/

8. Pharmaberater und Pharmareferent
§ 75 AMG: www.gesetze-im-internet.de/amg_1976/__75.html
§ 76 AMG: www.gesetze-im-internet.de/amg_1976/__76.html

9. BtM-Verantwortlicher
§ 3 BtMG: www.gesetze-im-internet.de/btmg_1981/__3.html
§ 5 Abs. 1 Nr. 1 und 2 BtMG: www.gesetze-im-internet.de/btmg_1981/__5.html
§ 6 BtMG: www.gesetze-im-internet.de/btmg_1981/__6.html
§ 7 BtMG: www.gesetze-im-internet.de/btmg_1981/__7.html

10. Person Responsible for Regulatory Compliance
Art. 15 Regulation (EU) 2017/745 (MDR): eur-lex.europa.eu/eli/reg/2017/745/oj/eng
Art. 15 Regulation (EU) 2017/746 (IVDR): eur-lex.europa.eu/eli/reg/2017/746/oj/eng

11. Medizinprodukteberater
§ 83 MPDG: www.gesetze-im-internet.de/mpdg/__83.html

12. Beauftragter für Medizinproduktesicherheit
§ 6 MPBetreibV: www.gesetze-im-internet.de/mpbetreibv_2025/__6.html

13. Strahlenschutzbeauftragter
§ 70 StrlSchG: www.gesetze-im-internet.de/strlschg/__70.html
§ 48 StrlSchV: www.gesetze-im-internet.de/strlschv_2018/__48.html

14. Gefahrgutbeauftragter
§ 3 GbV: www.gesetze-im-internet.de/gbv_2011/__3.html
§ 4 GbV: www.gesetze-im-internet.de/gbv_2011/__4.html
ADR 2025, subsection 1.8.3: unece.org/adr-2025-files

15. Verantwortliche Person (Kosmetik)
Art. 4 Regulation (EC) 1223/2009: eur-lex.europa.eu/eli/reg/2009/1223/oj/eng
Art. 5 Regulation (EC) 1223/2009: eur-lex.europa.eu/eli/reg/2009/1223/oj/eng

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